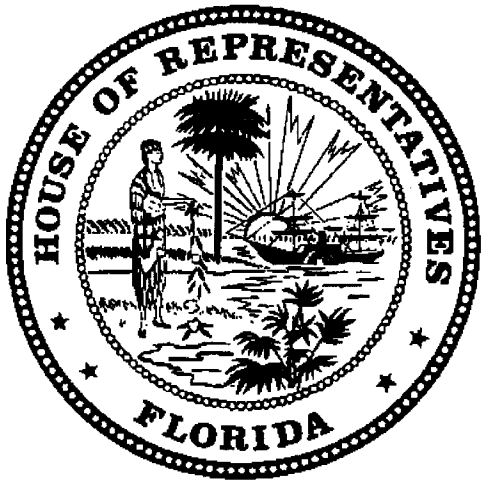

Health Care Regulation Committee

Tuesday, April 4, 2006
10:15 AM - 11:00 AM
212 Knott Building

Allan G. Bense
Speaker

Rene Garcia
Chair

House of Representatives

Committee on Health Care Regulation

AGENDA

April 4, 2006
10:15 AM - 11:00 AM
212 Knott Building

I. Opening Remarks by Chair Garcia

II. Consideration of the following bills:

HB 569 – Athletic Trainers by Rep. Kreegel

HB 775 – Psychologist Specialties by Rep. Roberson

HB 913 – Controlled Substances by Rep. Harrell

HB 943 – Public Records by Rep. Harrell

HB 1111 – Financial Responsibility of Advanced Registered Nurse Practitioners by Rep. Proctor

HB 1177 – Patient Handling and Moving Practices by Rep. Roberson

HB 1397 – Drug Distribution by Rep. Homan

HB 1625 – Clinical Perfusionists by Rep. Kottkamp

III. Closing Remarks

IV. Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 569 Athletic Trainers
SPONSOR(S): Kreegel
TIED BILLS: **IDEN./SIM. BILLS:** SB 266

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) PreK-12 Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 569 revises the licensure and renewal requirements for athletic trainers. The bill removes several provisions, including: an exemption relating to teacher apprentice athletic trainers; required supervised athletic training experience and continuing education in standard first aid; and a grandfather clause that allowed for an alternative avenue for individuals seeking licensure prior to October 1, 1996. The bill requires athletic trainers employed by a school district to be licensed under part XIII of ch. 468, F.S., as an athletic trainer.

The bill does not appear to have a fiscal impact on state or local governments.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill removes several regulations related to the standards of the profession of athletic training in Florida.

B. EFFECT OF PROPOSED CHANGES:

The bill amends the following provisions to s. 468.707, F.S., relating to licensure by examination for the profession of athletic training:

- Requires the completion of an approved athletic training curriculum from an accredited college or university, or a program approved by the board; and removes specific coursework requirements;
- Removes all requirements of direct supervision under a certified athletic trainer, and that the applicant must have practiced athletic training 3 out of the last 5 years; and removes the alternative to the direct supervision, that allows an individual to be certified by the National Athletic Trainers' Association or a comparable National Athletic standards organization; and
- Removes a grandfather clause that was created as an alternative pathway for licensure to individuals prior to October 1, 1996.

The bill amends s. 468.711, F.S., to delete the requirement that at the time of licensure renewal an athletic trainer must be certified in standard first aid.

The bill amends s. 468.723, F.S., to delete an exemption for the classification of teacher apprentice trainer I and II, that according to the Department of Education are no longer valid in s. 1012.46, F.S.

The bill amends s. 1012.46, F.S., to remove first responders and teacher athletic trainers as employment classifications within a school district's athletic injuries prevention and treatment program. The bill provides that a licensed athletic trainer *may* possess certification as an educator. So, a fully licensed athletic trainer employed by a school district is not required to have a teaching certificate issued by the Department of Education unless he or she is providing instruction. According to the Department of Education, this provides greater flexibility to school districts in the employment of licensed athletic trainers.

BACKGROUND

The Department of Health's Division of Medical Quality Assurance

The Department of Health's Division of Medical Quality Assurance (MQA) regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA supports licensure and disciplinary activities for 37 professions and 6 facilities, and works with 28 boards and councils. Boards are responsible for approving or denying applications for licensure and are involved in disciplinary hearings. The range of disciplinary actions taken by boards includes citations, suspensions, reprimands, probations, and revocations. Licensed athletic trainers are governed by rules adopted by the Board of Athletic Training.

Licensed Athletic Trainers in Florida

Section 468.707, F.S. provides the licensure by examination requirements for licensed athletic trainers in the state. Accordingly, the Department of Health may license an individual who:

- Has completed the application form and remitted the required fees, which may total $500;[1]
- Is at least 21 years of age;
- Has obtained a baccalaureate degree from a college or university accredited by an accrediting agency recognized and approved by the United States Department of Education or the Commission on Recognition of Postsecondary Accreditation, or approved by the board;
- Has completed coursework from an accredited college or university in each of the following areas, as provided by rule: health, human anatomy, kinesiology/biomechanics, human physiology, physiology of exercise, basic athletic training, and advanced athletic training;
- Is certified in standard first aid and cardiovascular pulmonary resuscitation (CPR) from the American Red Cross or an equivalent certification;
- Has, within 2 of the preceding 5 years, attained a minimum of 800 hours of athletic training experience under the direct supervision of a licensed athletic trainer or an athletic trainer certified by the National Athletic Trainers' Association or a comparable national athletic standards organization; and
- Has passed an examination administered or approved by the board.

The department may also grandfather in an individual who:
- Has completed the application form and remitted the required fees no later than October 1, 1996;
- Is at least 21 years of age;
- Is certified in standard first aid and cardiovascular pulmonary resuscitation from the American Red Cross or an equivalent certification;
- Has practiced athletic training for at least 3 of the 5 years preceding application; or
- Is currently certified by the National Athletic Trainers' Association or a comparable national athletic standards organization.

Pursuant to the requirements of s. 456.034, F.S., each applicant must complete a continuing education course on human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) as part of initial licensure.

Certified Athletic Trainers and the National Athletic Trainers' Association

According to the National Athletic Trainers' Association, certified Athletic Trainers are medical experts in preventing, recognizing, managing and rehabilitating injuries that result from physical activity. Athletic trainers can help athletes avoid unnecessary medical treatment and disruption of normal daily life.[2]

The American Medical Association (AMA) recognized athletic training as an allied health care profession in 1990. AMA recommends placement of certified athletic trainers in every high school to keep America's youth safe and healthy.[3] A certified athletic trainer specializes in six practice areas or domains:
- Prevention
- Recognition, Evaluation & Assessment
- Immediate Care
- Treatment, Rehabilitation & Reconditioning
- Organization & Administration
- Professional Development & Responsibility

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[1] See s. 468.709. F.S.
[2] Online at the National Athletic Trainers Association website: http://www.nata.org/downloads/documents/306CareerInfoBrochure.htm
[3] Ibid.

As part of a complete health care team, the certified athletic trainer works under the direction of a licensed physician and in cooperation with other health care professionals, athletics administrators, coaches and parents. The certified athletic trainer gets to know each athlete individually and can treat injuries more effectively.

A certified athletic trainer's day may, for example, include these tasks:

- Prepare athletes for practice or competition, including taping, bandaging and bracing;
- Evaluate injuries to determine their management and possible referral;
- Develop conditioning programs; and
- Implement treatment and rehabilitation programs.

Students who want to become certified athletic trainers must earn a degree from an accredited athletic training curriculum or meet other requirements set by the Board of Certification. A growing number of universities are gaining accreditation through the Commission on Accreditation of Allied Health Education Programs (CAAHEP).

The Athletic Trainer curriculum includes formal instruction in a variety of areas, such as:

- Assessment and Evaluation
- Acute Care
- General Medical Conditions and Disabilities
- Pathology of Injury and Illness
- Pharmacological Aspects of Injury and Illness
- Nutritional Aspects of Injury and Illness
- Therapeutic Exercise
- Therapeutic Modalities
- Risk Management and Injury Prevention
- Health Care Administration
- Professional Development and Responsibilities
- Psychosocial Intervention and Referral

The National Board of Certification for National Certification of Athletic Trainers

National Certification of Athletic Trainers Requires Continuing Education for National Certification

The Board of Certification (BOC) was incorporated in 1989 to provide a certification program for entry-level athletic trainers and recertification standards for certified athletic trainers. The National Certification of Athletic Trainers Examination is recognized in 40 states.

The BOC has established continuing education requirements that a certified athletic trainer is required to complete in order to maintain their status as a BOC certified athletic trainer.[4] Annually, the Board of Certification reviews the requirements for certification eligibility and standards for continuing education. The Board reviews and revises the certification examination every five years.

National Athletic Training Examination Requires Emergency Cardiac Care Certification

National Examination Candidates must be graduates of an accredited Athletic Training Curriculum Program. Candidates for certification must pass a three-part examination. The three parts are: written, simulation, and practical.

Until recently, individuals wishing to take Part 3 of the exam application were required to have a current CPR certification card. This requirement has been updated and requires that they have an Emergency Cardiac Care Certification (ECCC). ECCC must be current and include the following: adult & pediatric

[4] Online at the Board on Certification for Athletic Trainers at: http://www.bocatc.org/athtrainer/DEFINE/

CPR, airway obstruction, 2nd rescuer CPR, AED and barrier devices (e.g., pocket mask, bag valve mask). Organizations that provide the ECCC certification are: CPR/AED for the Professional Rescuer by the American Red Cross or BLS Healthcare Provider CPR by the American Heart Association. A valid EMT card may be substituted for the ECCC requirement.

C. SECTION DIRECTORY:

Section 1. Amends s. 468.707, F.S., to revise licensure by examination requirements.
Section 2. Amends s. 468.711, F.S., to revise licensure renewal and continuing education requirements.
Section 3. Amends s. 468.723, F.S., to provide that a person employed as an apprentice trainer or athletic trainer is not exempt from part XIII of ch. 468, F.S.
Section 4. Amends s. 1012.46, F.S., to provide for the replacement of teacher athletic trainers by licensed athletic trainers; remove a first responder classification; require that an athletic trainer employed by a school district must be licensed; and remove the provision that they must be certified as an educator.
Section 5. Provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

DRAFTING ISSUES:
Section 456.017(1)(c), F.S., prohibits the Department of Health and boards from administering a state-developed written examination if a national examination is available. On line 51, the bill provides "has passed an examination administered or approved by the board." It may be advantageous to update the language by removing the reference to "administered."

OTHER COMMENTS:
According to the Department of Health, courts have viewed licensure for health care practitioners as a property right. In practitioner licensure protocol, once an applicant is licensed, whether by examination, endorsement, or grandfathering, they will continue to be licensed as long as they meet the renewal criteria. Only if their license becomes null and void would they have to meet any new criterion that has been implemented since they were initially licensed. According to DOH, if the grandfather clause in s. 468.707(1)(b), F.S., is deleted, it is unclear as to the impact to individuals licensed in accordance with that grandfather clause when read against s. 468.711(1), F.S.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to athletic trainers; amending s. 468.707, F.S.; revising the requirements for licensure as an athletic trainer; amending s. 468.711, F.S.; revising the criteria for continuing education in athletic training; amending s. 468.723, F.S.; providing that a person employed as an apprentice trainer or athletic trainer is not exempt from part XIII of ch. 468, F.S.; amending s. 1012.46, F.S.; deleting the classification of first responder in a school district's athletic injuries prevention and treatment program; requiring that an athletic trainer employed by a school district be licensed as an athletic trainer; deleting a requirement that such person possess certain certification as an educator; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 468.707, Florida Statutes, is amended to read:

468.707 Licensure by examination; requirements.--

(1) Any person desiring to be licensed as an athletic trainer shall apply to the department on a form approved by the department.

~~(a)~~ The department shall license each applicant who:

(a)~~1.~~ Has completed the application form and remitted the required fees.

(b)~~2.~~ Is at least 21 years of age.

(c) ~~3.~~ Has obtained a baccalaureate degree from a college or university accredited by an accrediting agency recognized and approved by the United States Department of Education or the Commission on Recognition of Postsecondary Accreditation, or approved by the board.

(d) ~~4.~~ Has completed an approved athletic training curriculum ~~coursework~~ from a college or university accredited by an accrediting agency recognized and approved by the United States Department of Education or the Commission on Recognition of Postsecondary Accreditation, or approved by the board~~, in each of the following areas, as provided by rule: health, human anatomy, kinesiology/biomechanics, human physiology, physiology of exercise, basic athletic training, and advanced athletic training~~.

(e) ~~5.~~ Has current certification in ~~standard first aid and~~ cardiovascular pulmonary resuscitation from the American Red Cross or an equivalent certification as determined by the board.

~~6. Has, within 2 of the preceding 5 years, attained a minimum of 800 hours of athletic training experience under the direct supervision of a licensed athletic trainer or an athletic trainer certified by the National Athletic Trainers' Association or a comparable national athletic standards organization.~~

(f) ~~7.~~ Has passed an examination administered or approved by the board.

~~(b) The department shall also license each applicant who:~~

~~1. Has completed the application form and remitted the required fees no later than October 1, 1996.~~

~~2. Is at least 21 years of age.~~

~~3. Has current certification in standard first aid and cardiovascular pulmonary resuscitation from the American Red Cross or an equivalent certification as determined by the board.~~

~~4.a. Has practiced athletic training for at least 3 of the 5 years preceding application; or~~

~~b. Is currently certified by the National Athletic Trainers' Association or a comparable national athletic standards organization.~~

Section 2. Section 468.711, Florida Statutes, is amended to read:

468.711 Renewal of license; continuing education.--

(1) The department shall renew a license upon receipt of the renewal application and fee, provided the applicant is in compliance with the provisions of this part, chapter 456, and rules promulgated pursuant thereto.

(2) The board may, by rule, prescribe continuing education requirements, not to exceed 24 hours biennially. The criteria for continuing education shall be approved by the board and shall include a current certificate in ~~include 4 hours in standard first aid and~~ cardiovascular pulmonary resuscitation from the American Red Cross or equivalent training as determined by the board.

(3) Pursuant to the requirements of s. 456.034, each licensee shall complete a continuing education course on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure.

Section 3. Section 468.723, Florida Statutes, is amended to read:

468.723 Exemptions.--~~Nothing in~~ This part does not prevent or restrict ~~shall be construed as preventing or restricting~~:

(1) The professional practice of a licensee of the department who is acting within the scope of such practice.

(2) An athletic training ~~A~~ student ~~athletic trainer~~ acting under the direct supervision of a licensed athletic trainer.

~~(3) A person employed as a teacher apprentice trainer I, a teacher apprentice trainer II, or a teacher athletic trainer under s. 1012.46.~~

(3) ~~(4)~~ A person from administering standard first aid treatment to an athlete.

(4) ~~(5)~~ A person licensed under chapter 548, provided such person is acting within the scope of such license.

(5) ~~(6)~~ A person providing personal training instruction for exercise, aerobics, or weightlifting, if the person does not represent himself or herself as able to provide "athletic trainer" services and if any recognition or treatment of injuries is limited to the provision of first aid.

Section 4. Section 1012.46, Florida Statutes, is amended to read:

1012.46 Athletic trainers.--

(1) School districts may establish and implement an athletic injuries prevention and treatment program. Central to this program should be the employment and availability of persons trained in the prevention and treatment of physical injuries that ~~which~~ may occur during athletic activities. The program should reflect opportunities for progressive advancement and compensation in employment as provided in subsection (2) and

meet certain other minimum standards developed by the Department of Education. The goal of the Legislature is to have school districts employ and have available a full-time ~~teacher~~ athletic trainer in each high school in the state.

~~(2) To the extent practicable, a school district program should include the following employment classification and advancement scheme:~~

~~(a) First responder.--To qualify as a first responder, a person must possess a professional, temporary, part-time, adjunct, or substitute certificate pursuant to s. 1012.56, be certified in cardiopulmonary resuscitation, first aid, and have 15 semester hours in courses such as care and prevention of athletic injuries, anatomy, physiology, nutrition, counseling, and other similar courses approved by the Commissioner of Education. This person may only administer first aid and similar care.~~

(2) ~~(b) Teacher athletic trainer.--~~To qualify as an ~~a teacher~~ athletic trainer, a person must be licensed as required by part XIII of chapter 468 and may possess a professional, temporary, part-time, adjunct, or substitute certificate pursuant to s. 1012.35, s. 1012.56, or s. 1012.57~~, and be licensed as required by part XIII of chapter 468~~.

Section 5. This act shall take effect upon becoming a law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 569**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Kreegel offered the following:

Amendment (with directory and title amendments)

Remove line(s) 70 and insert:

compliance with the provisions of this section ~~part~~, chapter 456, and

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **HB 569**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Kreegel offered the following:

Amendment (with directory and title amendments)

Remove line(s) 45 and insert:

Cross, American Heart Association, or an equivalent certification as determined by the board.

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HB569-Kreegel2.doc

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 775 Psychologist Specialties
SPONSOR(S): Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1560

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Governmental Operations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 775 provides that a licensed psychologist under ch. 490, F.S., may not hold him or her self out as a board-certified specialist or diplomate unless they have received formal recognition from a specialty board of the American Board of Professional Psychology or other agency deemed equivalent by the Board of Psychology. The bill provides that a licensed psychologist may indicate the services offered and whether their practice is limited to one or more types of services, only if this reflects their scope of practice.

This bill does not appear to have a fiscal impact on state or local governments.

The bill will take effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard individual liberty and promote personal responsibility-The bill may provide protections to consumers from individuals who hold themselves out as a board-certified specialist or a diplomate, but have "suspect training" or "vanity credentials." Consumers would have a clearer idea of a psychologist's credentials. The bill clarifies that a licensed psychologist is permitted to advertise or state that their practice is limited to a specific type of service.

B. EFFECT OF PROPOSED CHANGES:

CURRENT SITUATION

The Department of Health licenses the practice of psychology, but does not license individuals by specialty. Because of this, the number of individuals in Florida with a specialty in psychology is unknown. Currently, there are 4,118 licensed psychologists in the state. A licensed psychologist in Florida must have a doctoral degree.[1] The doctoral degree may be in psychology or a doctoral–level degree in psychological education.[2]

According to a telephone conversation with staff of the American Psychology Association, the association recognizes that there is a problem nationally with individuals who hold themselves out as a board-certified specialist or a diplomate, but who have "suspect training" or "vanity credentials."

The American Psychology Association (APA) has discussed the possibility of developing criteria that may be used to identify an appropriate certifying body of legitimate psychology specialties. According to an email from the Deputy Executive Director for Education of the American Psychological Association, this issue has been discussed, but to date has not resulted in policy action by the APA.

EFFECTS OF THE BILL

The bill provides that a licensed psychologist regulated under ch. 490, F.S., may not hold themselves out as a board-certified specialist or diplomate unless they have received formal recognition from a specialty board of the American Board of Professional Psychology or other agency "deemed equivalent" by the Board of Psychology within the Department of Health.

Currently there are thirteen Specialty Boards recognized by the American Board of Professional Psychology (ABPP).[3] These boards are listed below: [4]

1. The American Board of Cognitive and Behavioral Psychology
2. The American Board of Clinical Psychology
3. The American Board of Clinical Child and Adolescent Psychology
4. The American Board of Clinical Health Psychology
5. The American Board of Clinical Neuropsychology
6. The American Board of Counseling Psychology
7. The American Board of Family Psychology
8. The American Board of Forensic Psychology

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[1] See ss. 490.005(1)(a)1., 490.006(1)(c) and 490.0051(1)(b), F.S.

[2] See s. 490.003(3), F.S.

[3] The American Board of Professional Psychology (ABPP) was incorporated in 1947 with the support of the American Psychological Association.

[4] According the ABPP, it should be noted that the practice activities in any specialty seldom are exclusive to the specialty and that most practice activities are shared with the general practice of professional psychology. The pattern of practice activities, including limiting the scope of practice, and focusing upon more complex or unique problems or technologies is more relevant in defining a specialty together with advanced education, training, and experience.

9. The American Board of Group Psychology
10. The American Board of Psychoanalysis in Psychology
11. The American Board of Rehabilitation Psychology
12. The American Board of School Psychology
13. The American Board of Organizational and Business Consulting Psychology

The bill provides that a licensed psychologist may indicate the services they offer and whether their practice is limited to one or more types of services, as long as it represents their scope of practice.

BACKGROUND

American Psychology Association

The American Psychology Association (APA) defines "psychology" as the study of the mind and behavior. The discipline embraces all aspects of the human experience — from the functions of the brain to social actions and from child development to care for the aged. In every conceivable setting from scientific research centers to mental health care services, "the understanding of behavior" is the enterprise of psychologists.

There are 53 professional divisions in the APA, which include such areas as:[5]

- Developmental Psychology
- School Psychology
- Rehabilitation Psychology
- Psychotherapy
- Psychology of Religion
- Clinical Neuropsychology
- Exercise and Sport Psychology
- Trauma Psychology
- Behavioral Analysis

What is the Practice of Psychology?

Section 490.003(4), F.S., defines the "practice of psychology" as the observation, description, evaluation, interpretation, and modification of human behavior, by the use of scientific and applied psychological principles, methods, and procedures, for the purpose of describing, preventing, alleviating, or eliminating symptomatic, maladaptive, or undesired behavior and of enhancing interpersonal behavioral health and mental or psychological health. The ethical practice of psychology includes, but is not limited to:

- Psychological testing and the evaluation or assessment of personal characteristics such as intelligence, personality, abilities, interests, aptitudes, and neuropsychological functioning, including evaluation of mental competency to manage one's affairs and to participate in legal proceedings;
- Counseling, psychoanalysis, all forms of psychotherapy, sex therapy, hypnosis, biofeedback, and behavioral analysis and therapy;
- Psychoeducational evaluation, therapy, remediation, and consultation; and
- Use of psychological methods to diagnose and treat mental, nervous, psychological, marital, or emotional disorders, illness, or disability, alcoholism and substance abuse, and disorders of habit or conduct, as well as the psychological aspects of physical illness, accident, injury, or disability, including neuropsychological evaluation, diagnosis, prognosis, etiology, and treatment.

C. SECTION DIRECTORY:

Section 1. Creates s. 490.0149, F.S., to specify the circumstances under which a psychologist may hold himself or herself out as a board-certified specialist or diplomate or offer specific types of services.
Section 2. Provides that the bill will take effect on July 1, 2006.

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II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See "D. Fiscal Comments" below.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Psychologists may have costs associated with changing their advertisements.

D. FISCAL COMMENTS:

The Department of Health, reports it may receive more complaints regarding practitioners who advertise inappropriately. While it is indeterminate how many complaints would be received, the department believes the number would be manageable. The department stated they would take steps to make sure that the licensees are made aware of this new provision.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   The bill requires the Board of Psychology to "deem equivalent" other recognizing agencies by rule. According to Article II, Section III of the Florida Constitution, this could be viewed as an improper delegation of authority. It is presumed that the Board may "deem equivalent" another recognizing agency by rule that the Joint Administrative Procedures Committee (JAPC) would recognize from the statutory language used. Guidelines or criteria should be included in statute to clarify the intent.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health with adequate rule-making authority to implement the provisions provided in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Concern has been raised that the bill will adversely impact individuals who hold a certification as a Behavioral Analyst. Behavioral analysts are *not* a health profession regulated by the Division of Medical Quality Assurance within the Department of Health. They are under the purview of the Agency for Persons with Disabilities and are listed as a Developmental Disabilities Services Program. This program was recently transferred from the Department of Children and Families (DCF), and the administrative rules for behavioral analysts are currently listed under DCF.[6]

Section 393.17, F.S., provides statutory authority to the Agency for Persons with Disabilities such that they *may* recognize the certification of behavior analysts awarded by a nonprofit corporation whose mission is to meet the professional credentialing needs identified by behavioral analysts, state governments, and consumers of behavioral analysis services and whose work has the support of the Association for Behavioral Analysis International.

Who is a behavioral analyst?
According to the Division of Behavior Analysis within the American Psychology Association (APA), behavior analysis promotes basic research, both animal and human, in the experimental analysis of behavior; it encourages the application of the results of such research to human affairs; and it cooperates with other disciplines whose interests overlap.

Behavior Analysis Certification Board (BACB)
A nonprofit corporation, independent of the APA, was established as a result of the identification of credentialing needs by behavior analysts, agencies in several states, and consumers of behavior analysis services. The purpose of the Behavior Analysis Certification Board's (BACB or "certification board") is to develop, promote, and implement a *voluntary* national certification program for behavior analyst practitioners. The certification board offers two certifications: the board certified associate behavior analyst who must have at least a bachelor's degree and the board certified behavior analyst who must have at least a master's degree.

According to the Executive Director of the Certification Board, they do not monitor whether the individuals who take the behavioral analysis certification board are licensed psychologists. So the impact of the bill on the number of licensed psychologists who also hold a valid certification as a behavioral analyst is unavailable.

The BACB sent an email to their members and received responses from *approximately 30 individuals* in the state claiming to be a licensed psychologist who also hold a valid certification as a behavioral analyst.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

[6] See 65B-4.023 and 65B4.025, F.A.C.

A bill to be entitled

An act relating to psychologist specialties; creating s. 490.0149, F.S.; specifying the circumstances under which a psychologist may hold himself or herself out as a board-certified specialist or diplomate or offer specific types of services; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 490.0149, Florida Statutes, is created to read:

490.0149 Specialties.--A psychologist licensed under this chapter may not hold himself or herself out as a board-certified specialist or diplomate unless the psychologist has received formal recognition as a specialist or diplomate from a specialty board of the American Board of Professional Psychology, Inc., or other recognizing agency deemed equivalent by the board. However, a licensed psychologist may indicate the services offered and may state his or her practice is limited to one or more types of services when this accurately reflects the scope of practice of the psychologist.

Section 2. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 775**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 490.0149, Florida Statutes, is created to read:

490.0149 Specialties.--

(1) As used in this section, the term "specialties" or "diplomate" means defined areas in the practice of psychology with recognized special competency acquired through an organized sequence of formal education, training, experience and professional standing.

(2) A person licensed as a psychologist or school psychologist may not hold himself or herself out as a certified psychology specialist or psychology diplomate unless the person has received formal recognition as a board certified psychology specialist or psychology diplomate from a recognized certifying body that has been approved by the board.

(3) The board shall adopt rules to establish criteria for approval of certifying bodies. The criteria, must include:

(a) Peer review and self-study;

(b) Established standards;

(c) Assessments of competencies characteristic of the specialty;

(d) Administrative support; and

(e) A unified relationship to the public and the profession.

(4) A person licensed under this chapter may indicate the services they offer and may state his or her practice is limited to one or more types of services when this accurately reflects their scope of practice.

Section 2. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to psychologist specialties; creating s. 490.0149, F.S.; providing a definition; specifying the circumstances under which a psychologist may hold himself or herself out as a certified psychology specialist or psychology diplomate; providing the board the authority to adopt rules and provide certain criteria for the approval of certifying bodies; specifying that an individual may specify the types of services they provide; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 913 Controlled Substances
SPONSOR(S): Harrell and others
TIED BILLS: HB 943 **IDEN./SIM. BILLS:** SB 178

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell ASB	Mitchell
2) Criminal Justice Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 913 requires the development and adoption of a counterfeit-resistant prescription blank to be used voluntarily by physicians to prescribe Schedule II, Schedule III, or Schedule IV controlled substances. The bill prohibits the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks. The bill provides additional requirements for the dispensing of a controlled substance. Most significantly, the bill:

- Provides that any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically. Such prescriptions must contain the date of the oral authorization.

- Provides that a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription.

- Limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply.

- Provides that each written prescription prescribed by a practitioner in Florida for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of the prescription.

Further, the bill provides that if a person dies of an apparent overdose, a law enforcement agency must prepare a report identifying each prescribed controlled substance listed in Schedule II, III or IV that is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. The law enforcement agency must submit a copy of the report to the medical examiner. A medical examiner who is preparing a report pursuant to s. 406.11, F.S. must include in the report information identifying each prescribed controlled substance listed in Schedule II, III or IV that was found in, on or near the deceased or among the deceased possessions.

The bill sponsor has indicated an amendment will be filed to create an electronic monitoring system for prescription of Schedule II, III, and IV controlled substances. **[See background information]**

The effective date of the bill is July 1, 2005.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill creates additional regulation regarding the dispensing of schedule II-IV prescription drugs; creates reporting requirements for law enforcement and medical examiners when a person dies of an apparent drug overdose; and creates a penalty for violations involving certain prescription blanks for controlled substances in schedules II-IV.

B. EFFECT OF PROPOSED CHANGES:

HB 913 creates a third degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts under the Florida Comprehensive Drug Abuse Prevention and Control Act, sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances adopted by rule by the Department of Health.

The bill amends section 893.04, F.S., as follows:

- The bill authorizes a pharmacist to record an oral prescription for controlled substances electronically.

- The bill provides that any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically. Such prescriptions must contain the date of the oral authorization. Currently, oral prescriptions must be promptly reduced to writing by the pharmacist.

- Under the provisions of the bill, a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription. Currently, there is no specific limitation on the length of supply of a Schedule III drug based on an oral prescription.

- The bill limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply. Currently, a Schedule II drug can only be dispensed upon a written prescription except in the case of an emergency which a Schedule II drug can be dispensed based on an oral prescription.

- Under the bill, a pharmacist is prohibited from dispensing a controlled substance in Schedule II, Schedule III, or Schedule IV to any patient or the patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid. The pharmacist may dispense a controlled substance in the exercise or her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

- The bill provides that each written prescription prescribed by a practitioner in Florida for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of the prescription. A pharmacist is permitted, upon verification by the prescriber, to document any information required on the prescription.

- The bill provides that a pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

HB 913 also specifies that the Department of Health (DOH) will develop counterfeit-resistant blanks for controlled substances that may be used by practitioners to prescribe controlled substances listed in Schedule II, Schedule III, or Schedule IV. DOH may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances.

If a person dies of an apparent drug overdose, the bill requires that a law enforcement agency shall prepare a report, which will be provided to the medical examiner, identifying each prescribed controlled substance that is found on or near the deceased or among the deceased's possession, and requires the law enforcement agency to identify the person who prescribed the drugs. The bill also requires that a medical examiner include in his or her report pursuant to s. 406.11, F.S., information identifying any Schedule II, Schedule III, or Schedule IV drug which is found in, on, or near the deceased or the deceased possessions.

CURRENT SITUATION

Florida Comprehensive Drug Abuse Prevention and Control Act

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Pharmaceutical Drug Dispensing

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.

Section 893.02, F.S., defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to

retain the prescription on file for a period of 2 years. The section requires the original container in which a controlled substance is dispensed to bear a label with specified information.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by regulation of DOH, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.[1] No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.[2] A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II.[3]

It is a first degree misdemeanor to distribute or dispense a controlled substance in violation of chapter 893, F.S., or to refuse or fail to make, keep, or furnish any record required under the chapter.[4]

Drug Overdose

Section 406.14, F.S., currently provides that any evidence material to the determination of the cause of death in possession of the law enforcement officers assigned to the investigation of the death must be made available to the medical examiner. The section provides that it is the duty of the law enforcement officer assigned to and investigating the death to immediately establish and maintain liaison with the medical examiner during the investigation of the cause of death. Section 406.11, F.S., provides that a district medical examiner must determine the cause of death of a human being in certain circumstances. The section does not require any particular information to be included in any report that the medical examiner creates.

Prescription Drug Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003. The National Institute on Drug abuse would like to reverse this trend by increasing awareness and promoting additional research on the topic.

Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system (CNS) depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

BACKGROUND

Legislative History

Over the last several years similar legislation has been filed in the House of Representatives and Senate. However, in past years the bill has included the creation of an electronic monitoring system for the prescription of controlled substances listed in Schedules II, III, and IV. The electronic monitoring system must be consistent with the American Society for Automation in Pharmacy. The proposed monitoring system relies upon pharmacists reporting the dispensing of Schedule II, Schedule III, or Schedule IV drugs as soon as possible after dispensing (but not to exceed 35 days). Pharmacies may

[1] Section 893.04(1)(f), F.S.
[2] Section 893.04(1)(g), F.S.
[3] See 21 CFR 1306.11 (d)(1) which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
[4] S. 893.03(7)(b), F.S.

report via electronic disk or tape. The database information is to be stored for up to 24 months before the information must be purged. The estimated fiscal impact for a statewide prescription monitoring database is approximately $2 million dollars.

Prescription Monitoring Systems

In an effort to control the diversion of controlled substances, over fifteen states have established prescription monitoring systems. Prescription monitoring systems collect prescription data from pharmacies in either paper or electronic format. The data may be reviewed and analyzed for educational, public health, and investigational purposes. The goals of prescription monitoring systems are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription monitoring program has its own set of goals for its program.

Prescription monitoring systems may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II; while others cover a range of controlled substances listed in Schedules II through V.

Potential Advantages of an Electronic Prescription Data Collection System

Potential advantages of an electronic prescription data collection system include the following:

- Identifies "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies. Doctor shopping is when a person continually switches physicians so that they can obtain enough of a drug to feed their addiction.
- Provides complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank, and set priorities for cases.
- Maximizes investigators' effectiveness by providing prescription data in a convenient, comprehensive, and timely method.
- Reduces intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns.
- Reduces the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists' dispensing patterns.

Potential Disadvantages of an Electronic Prescription Data Collection System

Some opponents of prescription monitoring systems dislike the concept of mandatory disclosure of protected health information and point to federal and state privacy laws as barriers to these monitoring systems.

There is a possibility that the tracking system could violate the Florida Constitution's Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides as follows:

Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

Unlike the penumbra or "implicit" privacy right of the federal constitution, Florida's privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal privacy provision, which contains a "penumbra" right of privacy created from the 1st, 3rd, 4th, 5th, and 9th amendments to the U.S. Constitution, extends only to such

fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and educating of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the federal constitution.[5]

Doctor Shoppers

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for non-medical use. People are obtaining these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it.

A data search indicated that no studies in the United States have specifically addressed the profile of a doctor shopper. A search of international data produced a report and findings from a study in Australia, which indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies. [6]

Frequent reasons used by doctor shoppers to obtain medicines are:

- Work hours interfere with sleep.
- Lost prescription.
- Relatives passed away.
- Migraine, cramp, toothache, or diarrhea.
- Just arrived in area.
- Handbag stolen.

Data shows that the age and gender of most doctor shoppers are as follows:

- 20% are aged between 15 and 29 years.
- 57% are aged between 30 and 49 years.
- 15% are aged between 50 and 64 years.
- 8% are 65 years and older.
- 58% are female.

C. SECTION DIRECTORY:

Section 1. – Creates s. 831.311, F.S., to provide violations involving certain prescription blanks.

Section 2. – Amends s. 893.04, F.S., relating to pharmacist prescribing practices.

Section 3. – Creates s. 893.065, F.S., relating to counterfeit-resistant prescription blanks.

Section 4. – Provides that the penalties created in s. 831.311, F.S., are effective only upon adoption of certain rules.

Section 5. – Creates an unnumbered section of law relating to drug overdose.

[5] See, In re T.W., 551 So.2d 1186 (Fla. 1989).
[6] www.hic.gov.au

Section 6. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   HB 913 makes it a third degree felony to sell, manufacture, alter, deliver or possess a counterfeit resistant prescription blank for controlled substances under certain circumstances. The offense is not ranked in the offense severity ranking chart of the Criminal Punishment Code. The criminal Justice Impact Conference has not met to consider the prison bed impact of this bill on the Department of Corrections. However, the conference generally determines that a bill which creates an unranked third degree felony will have an insignificant prison bed impact.

   The Department of Health has indicated that the fiscal impact of the bill is minimal.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Schedule III controlled substance prescriptions intended to cover more than a 30-day supply must be in writing under the bill. Consumers who currently obtain such drugs through an oral prescription may bear additional costs for medical visits to obtain prescriptions beyond a 30-day supply.

Practitioners opting to use the proposed counterfeit-proof prescription blank will likely pay a higher price than for customary prescription blanks.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule-making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill sponsor has indicated an amendment will be filed to create an electronic monitoring system for prescription of Schedule II, III, and IV controlled substance. **[See Background]**

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to controlled substances; creating s. 831.311, F.S.; prohibiting the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances; providing penalties; amending s. 893.04, F.S.; authorizing electronic recording of oral prescriptions for a controlled substance; providing additional requirements for the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV; creating s. 893.065, F.S.; requiring the Department of Health to develop and adopt by rule the form and content for a counterfeit-resistant prescription blank for voluntary use by practitioners to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV; providing contingent applicability of penalties; requiring reports of law enforcement agencies and medical examiners to include specified information if a person dies of an apparent overdose of a controlled substance listed in Schedule II, Schedule III, or Schedule IV; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 831.311, Florida Statutes, is created to read:

831.311 Violations involving certain prescription blanks for controlled substances in Schedules II-IV.--

(1) It is unlawful for any person with the intent to injure or defraud any person or to facilitate any violation of s. 893.13 to sell, manufacture, alter, deliver, utter, or possess any counterfeit-resistant prescription blank for controlled substances as provided in s. 893.065.

(2) Any person who violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 2. Section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.--

(1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(a) Oral prescriptions must be promptly reduced to writing or recorded electronically by the pharmacist.

(b) The written prescription must be dated and signed by the prescribing practitioner on the day when issued.

(c) There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:

1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.

2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.

3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.

4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.

5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6. The initials of the pharmacist filling the prescription and the date filled.

(d) The prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.

(e) Affixed to the original container in which a controlled substance is delivered upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:

1. The name and address of the pharmacy from which such controlled substance was dispensed.

2. The date on which the prescription for such controlled substance was filled.

3. The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.

4. The name of the prescribing practitioner.

5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.

6. The directions for the use of the controlled substance prescribed in the prescription.

7. A clear, concise warning that it is a crime to transfer

the controlled substance to any person other than the patient for whom prescribed.

(f) A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. No prescription for a controlled substance listed in Schedule II may be refilled.

(g) No prescription for a controlled substance listed in Schedule ~~Schedules~~ III, Schedule IV, or Schedule V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.

(2)(a) A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

(b) Any pharmacist who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV shall be exempt from the requirement to obtain suitable identification for the prescription dispensed by mail.

(c) Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral

prescription if, before filling the prescription, the pharmacist reduces the prescription to writing or records it electronically. Such prescriptions must contain the date of the oral authorization.

(d) Each written prescription from a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity on the face of the prescription and a notation of the date with the abbreviated month written out on the face of the prescription. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph.

(e) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.

(f) A pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

(3) ~~(2)~~ Notwithstanding the provisions of subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, in compliance with the provisions of s. 465.0275.

(4) ~~(3)~~ The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, or pharmacy. Such controlled substances may be sold only upon an order form, when such an order form is required for

sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.

Section 3. Section 893.065, Florida Statutes, is created to read:

893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedules II-IV.--The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank that may be used by practitioners to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Section 4. The penalties created in s. 831.311(2), Florida Statutes, by this act shall be effective only upon the adoption of the rules required pursuant to s. 893.065, Florida Statutes, as created by this act.

Section 5. If a person dies of an apparent drug overdose:

(1) A law enforcement agency shall prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03, Florida Statutes, that is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. Thereafter, the law enforcement agency shall submit a copy of

the report to the medical examiner.

(2) A medical examiner who is preparing a report pursuant to s. 406.11, Florida Statutes, shall include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03, Florida Statutes, that was found in, on, or near the deceased or among the deceased's possessions.

Section 6. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 913**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative Harrell offered the following:

Amendment (with title amendment)

Between line(s) 142 and 143 insert:

Section 3. Section 893.055, Florida Statutes, is created to read:

893.055 Electronic-monitoring system for prescription of controlled substances listed in Schedules II, III, and IV.--

(1) As used in this section, the term "pharmacy" means any pharmacy subject to licensure or regulation by the Department of Health pursuant to chapter 465 which dispenses or delivers a controlled substance included on Schedule II, Schedule III, or Schedule IV to a patient in this state.

(2) By June 30, 2007, the Department of Health shall contract for the design, and establishment, and maintenance of an electronic system consistent with standards of the American Society for Automation in Pharmacy to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV by health care practitioners within the state and

the dispensing of such controlled substances to an individual at a specific address within the state by a pharmacy permitted or registered by the Board of Pharmacy. The contracted vendor shall maintain the database within the United States.

(3) Any controlled substance listed in Schedule II, Schedule III, or Schedule IV which is dispensed to an individual in this state must be reported to the Department of Health's contract vendor through the system established pursuant to the requirements set forth in this section as soon thereafter as possible, but not more than 35 days after the date the controlled substance is dispensed, each time the controlled substance is dispensed. A pharmacy may meet the reporting requirements of this section by providing to the Department of Health's contract vendor an exchangeable electronic disc, electronic file, or tape of each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses.

(4) This section does not apply to controlled substances:

(a) Administered by a health care practitioner directly to a patient.

(b) Dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of no more than 72 hours.

(c) Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit.

(d) Ordered from an institutional pharmacy permitted under s. 465.019 in accordance with the institutional policy for such controlled substances or drugs.

(e) Dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(f) Prescribed by a health care practitioner for a patient younger than 16 years of age.

(5) The data required to be reported under this section shall be determined by the Department of Health by rule but may include any data required under s. 893.04.

(6) A practitioner or pharmacist who dispenses a controlled substance under this section must submit the information required by this section in an electronic or other format approved by rule of the Department of Health. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, compact discs, zip-drive storage, regular electronic mail, magnetic tapes, diskettes, and facsimile charges. The information submitted to the Department of Health's contract vendor under this section may be transmitted to any person or agency authorized to receive it pursuant to section 1 of House Bill 943, or similar legislation, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All transmissions required by this subsection must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain it for longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(7) Any contractor entering into a contract under s.893.055 is liable in tort with respect to the improper release of any confidential information received and for any breach of contract. Sovereign immunity may not be raised by the contractor, or the insurer of that contractor on the contractor's behalf, as a defense in any action arising out of the performance of any contract entered into under s.893.055 or as a defense in tort, or any other application, with respect to the maintenance of confidentiality of information and for any breach of contract.

(8) Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9) The Department of Health and the regulatory boards for the health care practitioners subject to this section shall adopt rules pursuant to s. 120.536(1) and 120.54 to administer this section.

(10) All costs incurred by the Department of Health in administering the prescription-monitoring system shall be borne by the department, and an amount necessary to cover such costs shall be appropriated annually, subject to the availability of funds, from the Grants and Donations Trust Fund. The Medical Quality Assurance Trust Fund may not be used to administer or otherwise fund this program.

(11) This section shall stand repealed on October 2, 2009, unless reviewed and saved from repeal through reenactment by the Legislature.

Amendment No. 1 (for drafter's use only)

========== T I T L E A M E N D M E N T ==========

Remove line 10 and insert:

Schedule II, Schedule III, or Schedule IV; creating s. 893.055, F.S.; providing a definition; requiring the Department of Health to establish an electronic system to monitor the prescribing of controlled substances listed in Schedules II, III, and IV; requiring the dispensing of such controlled substances to be reported through the system; providing exceptions; providing reporting requirements; providing penalties; requiring that the department and regulatory boards adopt rules; requiring the department to cover all costs for the system; providing for annual appropriations, subject to availability of funds; prohibiting using funds from the Medical Quality Assurance Trust Fund to administer the program; creating s.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 943 Public Records
SPONSOR(S): Harrell
TIED BILLS: HB 913 **IDEN./SIM. BILLS:** CS/SB 176

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AEB	Mitchell
2) Criminal Justice Committee			
3) Governmental Operations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 943 creates s. 893.056, F.S., to provide a public records exemption for certain information in the proposed electronic monitoring system of Schedule II, III, and IV prescription drugs. The exempt information is:

- Personal identifying information of a patient;
- A practitioner as defined in s. 893.02, F.S.; and
- A pharmacist as defined in s. 465.003, F.S.

The bill provides that the exempt records may be disclosed to certain entities, and the bill establishes criminal provisions for violating the bill.

HB 943 is linked to HB 913. HB 913 currently does not create an electronic prescription monitoring system. The bill sponsor has indicated an amendment to HB 913 will be filed to create an electronic monitoring system for prescription of Schedule II, III, and IV substances.

The bill requires a two-thirds vote of the members present and voting for passage.

The bill provides for future review and repeal of the exemption on October 2, 2011; provides a statement of public necessity; and provides a contingent effective date of July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill limits access to patient records.

B. EFFECT OF PROPOSED CHANGES:

HB 943 creates s. 893.056, F.S., to provide a public records exemption for certain information in the proposed electronic monitoring system of Schedule II-IV prescription drugs. The exempt information in the proposed electronic monitoring system is:

- Personal identifying information of a patient;
- A practitioner as defined in s. 893.02, F.S.; and
- A pharmacist as defined in s. 465.003, F.S.

The bill provides that the exempt records may be disclosed to:

- The Agency for Health Care Administration when it has initiated a review of specific identifiers of Medicaid fraud and abuse;
- A state or federal criminal justice agency that enforces laws relating to drugs and that is engaged in a specific investigation involving a violation of law;
- A practitioner defined under chapter 893, F.S., and an employee of the practitioner, who requests such information and certifies that it is necessary to provide medical treatment to a current patient, subject to the patient's written consent;
- A pharmacist licensed in this state, or a pharmacy intern or pharmacy technician designated by the pharmacists, who requests information and certifies that it is to be used to dispense controlled substances to a current patient; and
- The patient who is identified in the record, upon a written request, for the purpose of verifying that information.

The bill provides for future review and repeal of the exemption on October 2, 2011, pursuant to the Open Government Sunset Review Act of 1995, s. 119.15, F.S . It also provides a statement of public necessity and provides an effective date.

The effective date of the bill is July 1, 2006, and is linked to the passage of HB 913.

HB 913

HB 913 requires the development and adoption of counterfeit-resistant prescription blanks to be used voluntarily by physicians to prescribe Schedule II, Schedule III, or Schedule IV controlled substances. The bill prohibits the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks. The bill provides additional requirements for the dispensing of a controlled substance. Most significantly, the bill:

- Provides that any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically. Such prescriptions must contain the date of the oral authorization.

- Provides that a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription.

- Limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply.

- Provides that each written prescription prescribed by a practitioner in Florida for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of the prescription.

Further, the bill provides that if a person dies of an apparent overdose, a law enforcement agency must prepare a report identifying each prescribed controlled substance listed in Schedule II, III or IV that is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. The law enforcement agency must submit a copy of the report to the medical examiner. A medical examiner who is preparing a report pursuant to s. 406.11, F.S. must include in the report information identifying each prescribed controlled substance listed in Schedule II, III or IV that was found in, on or near the deceased or among the deceased possessions.

HB 941 is linked to HB 913. HB 913 currently does not create an electronic prescription monitoring system. The bill sponsor has indicated an amendment will be filed to create an electronic monitoring system for prescription of Schedule II, III, and IV substances.

C. SECTION DIRECTORY:

Section 1. – Creates s. 893.056, F.S., to create a public records exemption for the electronic monitoring system for prescription of controlled substances listed in Schedules II-IV.

Section 2. – Provides a statement of public necessity.

Section 3. – Provides an effective date of July 1, 2006 contingent on passage of HB 943.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

Article I, s. 24(c) of the Florida Constitution, requires a two-thirds vote of the members present and voting for passage of a newly created public records or public meetings exemption. Thus, the bill requires a two-thirds vote for passage.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Public Records and Public Meetings Laws

Article I, s. 24(a), Florida Constitution, sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. Article I, s. 24(b), Florida Constitution, sets forth the state's public policy regarding access to government meetings. The section requires all meetings of the executive branch and local government be open and noticed to the public.

The Legislature may, however, provide by general law for the exemption of records and meetings from the requirements of Article I, s. 24, Florida Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.

Public policy regarding access to government records and meetings is also addressed in the Florida Statutes. Section 119.07(1), F.S., also guarantees every person a right to inspect, examine, and copy any state, county, or municipal record, and s. 286.011, F.S., requires that all state, county, or municipal meetings be open and noticed to the public. Furthermore, the Open Government Sunset Review Act of 1995[1] provides that a public records or public meetings exemption may be created or maintained only if it serves an identifiable public purpose, and may be no broader than is necessary to meet one of the following public purposes:

- Allowing the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protecting sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety. However, only the identity of an individual may be exempted under this provision; or,
- Protecting trade or business secrets.

[1] Section 119.15, F.S.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to public records; creating s. 893.056, F.S.; exempting from public-records requirements information and records reported to the Department of Health under the electronic-monitoring system for prescription of controlled substances listed in Schedules II-IV; authorizing certain persons and entities access to personal identifying information of a patient; providing guidelines for the use of such information and penalties for violations; providing for future legislative review and repeal; providing a finding of public necessity; providing a contingent effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 893.056, Florida Statutes, is created to read:

893.056 Public-records exemption for the electronic-monitoring system for prescription of controlled substances listed in Schedules II-IV.--

(1) Personal identifying information of a patient, a practitioner as defined in s. 893.02, or a pharmacist as defined in s. 465.003, which is contained in records held by the Department of Health under s. 893.055, the electronic-monitoring system for prescription of controlled substances, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2) The Department of Health shall disclose such

confidential and exempt information to:

(a) The Agency for Health Care Administration when it has initiated a review of specific identifiers of Medicaid fraud and abuse.

(b) A criminal justice agency as defined in s. 119.011, which enforces the laws of this state or the United States relating to controlled substances and which has initiated an active investigation involving a specific violation of law.

(c) A practitioner as defined in s. 893.02, or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, who requests such information and certifies that the information is necessary to provide medical treatment to a current patient in accordance with s. 893.05, subject to that patient's written consent.

(d) A pharmacist as defined in s. 465.003, or a pharmacy intern or pharmacy technician who is acting on behalf of and at the direction of the pharmacist, who requests such information and certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with s. 893.04.

(e) The patient who is identified in the record upon a written request for the purpose of verifying that information.

(3) Any agency that obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information; however, the Agency for Health Care Administration or a criminal justice agency with lawful access to such information may disclose confidential and exempt information received from the Department

of Health to a criminal justice agency as part of an active investigation of a specific violation of law.

(4) Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

(5) This section is subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, and shall stand repealed on October 2, 2011, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that personal identifying information of a patient, a practitioner as defined in s. 893.02, Florida Statutes, or a pharmacist as defined in s. 465.003, Florida Statutes, contained in records that are reported to the Department of Health under s. 893.055, Florida Statutes, the electronic-monitoring system for prescription of controlled substances, be made confidential and exempt. Information concerning the prescriptions that a patient has been prescribed is a private, personal matter between the patient, the practitioner, and the pharmacist. Nevertheless, reporting of prescriptions on a timely and accurate basis by practitioners and pharmacists will ensure the ability of the state to review and provide oversight of prescribing and dispensing practices. Further, the reporting of this information will facilitate investigations and prosecutions of violations of state drug laws by patients, practitioners, or pharmacists, thereby increasing compliance with those laws. If, in the process, however, the information that would identify a patient is not made confidential and exempt, any person could

inspect and copy the record and be aware of the prescriptions that a patient has been prescribed. The availability of such information to the public would result in the invasion of the patient's privacy. If the identity of the patient could be correlated with his or her prescriptions, it would be possible for the public to become aware of the diseases or other medical concerns that a patient is being treated for by his or her physician. This knowledge could be used to embarrass or to humiliate a patient or to discriminate against him or her. Requiring the reporting of prescribing information, while protecting a patient's personal identifying information, will facilitate efforts to maintain compliance with the state's drug laws and will facilitate the sharing of information between health care practitioners and pharmacists, while maintaining and ensuring patient privacy. Additionally, exempting personal identifying information of doctors and pharmacists will ensure that an individual will not be able to "doctor-shop," that is to determine which doctors prescribe the highest amount of a particular type of drug and to seek those doctors out in order to increase the likelihood of obtaining a particular prescribed substance. Further, protecting personal identifying information of pharmacists ensures that an individual will not be able to identify which pharmacists dispense the largest amount of a particular substance and target that pharmacy for robbery or burglary. Thus, the Legislature finds that personal identifying information of a patient, a practitioner as defined in s. 893.02, Florida Statutes, or a pharmacist as defined in s. 465.003, Florida Statutes, contained in records reported under

s. 893.055, Florida Statutes, must be confidential and exempt from disclosure.

Section 3. This act shall take effect July 1, 2006, if House Bill 913, or similar legislation establishing an electronic system to monitor the prescribing of controlled substances, is adopted in the same legislative session or an extension thereof and becomes law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 943**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Harrell offered the following:

Amendment (with directory and title amendments)

Remove line(s) 24-65 and insert:

Department of Health or the Department of Health's contract vendor under s. 893.055, the electronic-monitoring system for prescription of controlled substances, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2) The Department of Health or the contract vendor entering into a contract pursuant to s. 893.055(1) shall disclose such confidential and exempt information to:

(a) The executive director, or a board investigator as designated by each board of the regulatory boards of the health care practitioners subject to s. 893.055 pursuant to the provisions of s. 456.073.

(b) The Agency for Health Care Administration when it has initiated a review of specific identifiers of Medicaid fraud and abuse.

(c) A criminal justice agency as defined in s. 119.011, which enforces the laws of this state or the United States relating to controlled substances and which has secured a subpoena for such confidential and exempt information pursuant to an active investigation of an individual involving a specific violation of law.

(d) A practitioner as defined in s. 893.02, or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, who requests such information and certifies that the information is necessary to provide medical treatment to a current patient in accordance with s. 893.05, subject to that patient's written consent.

(e) A pharmacist as defined in s. 465.003, or a pharmacy intern or pharmacy technician who is acting on behalf of and at the direction of the pharmacist, who requests such information and certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with s. 893.04.

(f) The patient who is identified in the record upon a written request for the purpose of verifying that information.

(3) Any agency that obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information; however, the Agency for Health Care Administration or a criminal justice agency with lawful access to such information may disclose confidential and exempt information received from the Department of Health to a criminal justice agency as part of an active investigation of a specific violation of law.

(4) Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

(5) This section is subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, and shall stand repealed on October 2, 2009, unless reviewed and saved from repeal through reenactment by the Legislature.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1111 Financial Responsibility of Advanced Registered Nurse Practitioners
SPONSOR(S): Proctor
TIED BILLS: **IDEN./SIM. BILLS:** SB 2212

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Halperin	Mitchell
2) Judiciary			
3) Health Care Appropriations			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 1111 creates s. 464.028, F.S., to provide an exemption for licensed Advanced Registered Nurse Practitioners (ARNPs) from the requirement to either carry medical malpractice insurance or self-insure through a line of credit, under certain circumstances. The terms "exemption" and "uninsured" refer to those ARNPs who neither carry malpractice insurance nor self-insure through a line of credit.

According to the DOH, ARNPs have experienced increased liability exposure in the past two years, and costs of liability have doubled or tripled during this same time frame.[1] As a consequence, licensees report increased difficulty in obtaining liability insurance at affordable rates, if at all. These difficulties have caused some ARNPs to discontinue their practice; and are especially problematic for ARNPs in rural and underserved areas of Florida who are not covered by a facility umbrella liability policy.

The bill requires that uninsured licensees post notice in the waiting room or provide a written statement to potential patients disclosing the lack of malpractice insurance. The bill further requires that ARNPs pay malpractice claims of certain amounts under specified conditions: up to $100,000 if he or she does not maintain hospital staff privileges or $250,000 if the licensee maintains hospital staff privileges. The bill specifies the time frame and process for probable cause judgments and licensee appeals; and requires the Department of Health (DOH) to oversee disciplinary actions.

According to the Department of Health, the bill has an indeterminate fiscal impact.

The effective date of the bill is July 1, 2006.

[1] Department of Health analysis on HB 1111, March 14, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – The bill removes a current requirement for ARNPs to carry liability protection through either malpractice insurance or a line of credit, and permits them to self-insure. At the same time, the bill increases the responsibilities of the DOH to regulate malpractice claims against ARNPs.

Safeguard individual liberty – The bill removes the requirement for ARNPs to self-insure, which may decrease the likelihood of judgment payout in malpractice suits.

B. EFFECT OF PROPOSED CHANGES:

Advanced Registered Nurse Practitioners are currently required to carry liability protection through either medical malpractice insurance or through a line of credit. HB 1111 creates s. 464.028, F.S., to provide an exemption from these requirements under certain circumstances. For ARNPs who choose to practice without coverage, the bill requires that he or she post notice in the waiting room or provide a written statement to potential patients disclosing the lack of malpractice insurance.

The bill sets minimum financial responsibility requirements of $100,000 for ARNPs without hospital staff privileges or $250,000 for ARNPs with hospital staff privileges. This payment would be due within 60 days after a malpractice judgment becomes final.

The bill requires the Department of Health to notify a licensee of possible disciplinary actions upon notification of an unsatisfied judgment; and requires the department to issue an emergency order suspending the license and certification of any licensee who fails to pay a claim or file an appeal within 30 days of notice. The bill provides that the probable cause panel must determine at its next meeting whether to take disciplinary action against the licensee. Penalties may include probation of the license, payments to the judgment creditor on a schedule determined by the board, or suspension of the license and certification for up to 5 years.

The department must provide an agreed upon schedule for payment or proof of appeal; and requires that the department reinstate the licensee's license and certification after proof of payment or a payment schedule is received.

The effective date of the bill is July 1, 2006.

PRESENT SITUATION

According to the DOH, ARNPs have experienced increased liability exposure in the past two years, and costs of liability have doubled or tripled during this same time frame.[2] Many insurance underwriters are looking to decrease their risk by not writing new policies for ARNPs in Florida, by canceling coverage, limiting the amount of coverage, or by raising premiums.[3] As a consequence, licensees report increased difficulty in obtaining liability insurance at affordable rates, if at all. These difficulties have caused some ARNPs to discontinue their practice; and are especially problematic for ARNPs in rural and underserved areas of Florida who are not covered by a facility umbrella liability policy.

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[2] Department of Health analysis on HB 1111, March 14, 2006.

[3] *Florida Nurse Practitioner Network.* "Professional Liability Insurance for Nurse Practitioners in Florida: Two Issues: Policies and Bad Information in Print." December 2005. www.fnpn.org/~main/id43.html

Current ARNP Financial Responsibility and Licensing Requirements

Section 456.048, F.S., requires ARNPs to carry malpractice insurance coverage or liability protection through a line of credit as a requisite for licensure and licensure renewal. The Board of Nursing is required by rule to determine the amount and manner of insurance sufficient to cover claims arising out of the rendering or failure to render professional care. All licensees must submit such proof as a condition of license renewal. ARNPs may meet this requirement by purchasing malpractice insurance, by getting a letter of credit, or by demonstrating exemption based on certain circumstances.

ARNP's must be covered in one of the following capacities[4]:

1. Carry professional liability coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000. Policies may be written from an authorized insurer, a surplus lines insurer, a joint underwriting association, a self-insurance plan, or a risk retention group;[5] or

2. Attain an unexpired irrevocable letter of credit[6] in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000 and which is payable to the ARNP as beneficiary.

Exemptions from Financial Responsibility

Exemptions from financial responsibility are provided in s. 456.048(2), F.S. An ARNP must meet one of the following criterions to be exempt from the malpractice requirements:

1. Practice exclusively as an officer, employee, or agent of the Federal Government or of the state or its agencies or its subdivisions, or as a volunteer;[7]
2. Have a license or certification that has become inactive;
3. Hold a limited license and practice under the scope of such limited license;[8]
4. Practice only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals;
5. Does not practice in the State of Florida; or
6. Can demonstrate that he or she has no malpractice exposure in the state.

Consequences of Self-Insurance or "Going Bare"

Currently in Florida, all health care professionals[9] except for physicians are required to maintain financial responsibility and do not have the option to carry a license without malpractice insurance. Experiences of physicians in "going bare" may suggest implications for ARNPs receiving this option. According to the Board of Medicine, approximately seven percent of Florida's physicians chose to go without insurance in 2004. Certain regions of the state have higher levels; for example, it was estimated that in Broward and Miami-Dade Counties between one-third and one-half of physicians were without liability insurance in 2005.[10]

The Department of Health reports that in the past eight years there have been five cases involving judgments against physicians without insurance. In each of these cases, the Board of Medicine required suspension of the licensee until proof of payment, or until a payment plan for the judgment

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[4] Rule 64B9-4.002(5)(a), Florida Administrative Code

[5] "Authorized insurer" is defined in s. 624.09, F.S; "surplus lines insurer" is defined in s. 626.914(2), F.S.; "joint underwriting association" is defined in s. 627.351(4), F.S., "self insurance plan" is defined in s. 627.357, F.S; and "risk retention group" is defined in s. 627.942, F.S.

[6] As defined by Chapter 675, F.S.

[7] Employee defined in s. 768.28(9)(b), F.S. and volunteer is defined in s. 110.501(1), F.S.

[8] Limited licenses are defined in s. 456.015, F.S.

[9] Acupuncturists, chiropractors, podiatrists, midwives, dentists, and advanced registered nurse practitioners, under Florida statute, do not have the option to fulfill their financial responsibility through self-insurance.

[10] "Doctors HUG or go bare" by John Dorschner, *Miami Herald,* July 18, 2005.

was provided. There have been a few cases of self-insured physicians who, when faced with a judgment against them, went bankrupt instead of paying the injured patient.[11] Courts have not consistently found hospitals liable for physicians who refuse to pay a judgment against them, but courts have noted the growing controversy.[12]

Different Criterion for Physicians Exemptions

The exemptions from financial responsibility for physicians to "go bare" are more extensive than those provided for ARNPs in HB 1111. In addition to the exemptions described for ARNPs above, physicians must also meet all of the following criteria in order to "go bare":

- Physicians hold an active license to practice in this state or another state or some combination thereof for more than 15 years;
- Physicians are retired or maintain part-time practice of no more than 1000 patient contact hours per year;
- Physicians have had no more than two claims resulting in an indemnity exceeding $10,000 within the previous five-year period;
- Physicians have not been convicted of or pled guilty to any criminal violation specified in Chapter 458 or 459, F.S.; and
- Physicians have not been subject, within the past ten years of practice, to license revocation or suspension, probation for a period of three years or longer, or a fine of $500 or more for a violation of Chapter 458 or 459, F.S., or the medical practice act of another jurisdiction.

C. SECTION DIRECTORY:

Section 1. Creates s. 464.028, F.S: provides for exempting licensed ARNPs from medical malpractice insurance requirements under specified circumstances; requires licensees to pay medical malpractice judgment amounts when rendered; increases Board of Nursing disciplinary procedures.

Section 2. Provides enacting date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to the Department of Health this bill would increase the number of emergency suspension orders and disciplinary actions against ARNPs. Because the actual increased number is indeterminate, the department cannot estimate the increase in enforcement costs against ARNPs who do not comply with the requirements of this bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

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[11] Daily Business Review, *Hospitals off hook for doctor's malpractice,* March 9, 2005.
[12] See *Baker v. Tenet Healthsystem Hospital Inc.*, 780 So.2d 170, 2001; *Robert v. A. Paschall,* 767 So.2d, 2000; and *Mercy Hospital v. Baumgardner,* 870 So. 2d 130, 2004.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

According to the Department of Health, there will be a minimal fiscal impact for rule promulgation which can be covered with existing resources.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None required.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Impact on the Department of Health

The DOH reports that this bill will require the department to create forms and have those forms officially adopted. The creation and approval of these forms could take as long as 90 days after the enactment of the law. Therefore, the department requests the effective date be changed to October 1, 2006.

Stakeholder Opinions

Proponents of the bill express concerns over the availability and affordability of malpractice insurance for ARNPs, and have noted the different standards for ARNPs and physicians to carry insurance coverage. Proponents argue that problems of availability and the cost of insurance are driving much needed health professionals out of the state.

Opponents of the bill express concerns that physicians who "go-bare" are hurting health care consumers, and that the same problems would occur if ARNPs were allowed to do so. They argue that when there are judgments against a "bare" practitioner and the practitioner does not pay, the injured patients and families receive no compensation.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to financial responsibility of advanced registered nurse practitioners; creating s. 464.028, F.S.; providing for exempting licensed advanced registered nurse practitioners from certain medical malpractice insurance requirements under certain circumstances; providing criteria; requiring licensees to pay certain medical malpractice judgment amounts under certain circumstances; requiring the Department of Health to notify a licensee of possible disciplinary action under certain circumstances; providing requirements; requiring the department to suspend the license and certification of such licensed practitioners for certain failures to comply; providing duties of a probable cause panel relating to disciplinary actions against a licensee; requiring the Board of Nursing to take certain disciplinary actions against a licensee under certain circumstances; authorizing the board to remove certain restrictions on a license and certification; requiring certain licensees to post a notice disclosing lack of medical malpractice insurance under certain circumstances; specifying notice contents; requiring the department to suspend the license and certification of a licensee for failing to pay certain judgments or awards for damages; providing for reinstatement of the license and certification; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 464.028, Florida Statutes, is created to read:

464.028 Financial responsibility of advanced registered nurse practitioners; exemption.--

(1)(a) Any person holding an active license and certification to practice as an advanced registered nurse practitioner under s. 464.012 who meets the criteria of paragraph (b) may be exempt from the requirement to maintain medical malpractice insurance as prescribed in s. 456.048 or by rule of the board.

(b) Upon the entry of an adverse final judgment arising from a medical malpractice arbitration award, from a claim of medical malpractice in contract or in tort, or from noncompliance with the terms of a settlement agreement arising from a claim of medical malpractice in contract or in tort, the licensee shall pay the judgment creditor the lesser of the entire amount of the judgment with all accrued interest or $100,000 if the advanced registered nurse practitioner is licensed pursuant to this chapter but does not maintain hospital staff privileges or $250,000 if the advanced registered nurse practitioner is licensed pursuant to this chapter and maintains hospital staff privileges, within 60 days after the date such judgment becomes final and subject to execution, unless otherwise mutually agreed to by the parties. Such adverse final judgment shall include any cross claim, counterclaim, or claim for indemnity or contribution arising from the claim of medical malpractice. Upon notification of the existence of an

unsatisfied judgment or payment pursuant to this paragraph, the department shall notify the licensee by certified mail that he or she shall be subject to disciplinary action unless, within 30 days after the date of mailing, he or she:

1. Shows proof that the unsatisfied judgment has been paid in the amount specified in this paragraph; or

2. Provides the department a copy of a timely filed notice of appeal, and:

a. A copy of a supersedeas bond properly posted in the amount required by law; or

b. An order from a court of competent jurisdiction staying execution on the final judgment pending disposition of the appeal.

(2) The department shall issue an emergency order suspending the license and certification of any licensee who, after 30 days following the receipt of a notice from the department, has failed to:

(a) Satisfy a medical practice claim against him or her; or (b) Provide the Department of Health:

1. A copy of a timely filed notice of appeal; and

2.a. A copy of a supersedeas bond properly posted in the amount declared by law; or

b. An order from a court of competent jurisdiction staying execution on the final judgment pending disposition of the appeal.

(3) Upon the next meeting of a probable cause panel of the board following 30 days after the date of mailing the notice of disciplinary action to the licensee, the panel shall make a

determination of whether probable cause exists to take disciplinary action against the licensee pursuant to subsection (2).

(4) If the board determines that the factual requirements of subsection (2) are met, the board shall take such disciplinary action against the licensee as the board deems appropriate. Such disciplinary action shall include, at a minimum, probation of the license with the restriction that the licensee must make payments to the judgment creditor on a schedule determined by the board to be reasonable and within the financial capability of the licensee. Notwithstanding any other disciplinary action imposed, the disciplinary penalty may include suspension of the license and certification for a period not to exceed 5 years. If an agreement to satisfy a judgment has been met and the licensee has completed a form supplying any necessary information required by the department, the board may remove any restriction on the license and certification.

(5) A licensee who meets the requirements of this section shall post a notice in the form of a sign prominently displayed in the reception area and clearly noticeable by all patients or provide a written statement to any person to whom advanced registered nurse practitioner services are provided stating: "Under Florida law, advanced registered nurse practitioners (ARNPs) are generally required to carry medical malpractice insurance or otherwise demonstrate financial responsibility to cover potential claims for medical malpractice. YOUR ADVANCED REGISTERED NURSE PRACTITIONER HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE INSURANCE. This is permitted under Florida law

subject to certain conditions. Florida law imposes penalties against noninsured advanced registered nurse practitioners who fail to satisfy adverse judgments arising from claims of medical malpractice. This notice is provided pursuant to Florida law."

(6) Notwithstanding any other provision of this section, the department shall suspend the license and certification of any advanced registered nurse practitioner against whom has been entered a final judgment, arbitration award, or other order or who has not entered into a settlement agreement to pay damages arising out of a claim for medical malpractice, if all appellate remedies have been exhausted and payment of up to the amounts required by this section has not been made within 30 days after the entering of such judgment, award, order, or agreement until proof of payment is received by the department or a payment schedule has been agreed upon by the advanced registered nurse practitioner and the claimant and presented to the department. After proof of payment is received by the department or a payment schedule has been agreed upon by the advanced registered nurse practitioner and the claimant and presented to the department, the department shall reinstate the licensee's license and certification.

Section 2. This act shall take effect July 1, 2006.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1177 Patient Handling and Moving Practices
SPONSOR(S): Roberson and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2244

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AJB	Mitchell
2) Elder & Long-Term Care Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 1177 address staff back injuries in hospitals and nursing homes. According to the Bureau of Labor Statistics, nursing personnel are consistently listed as one of the top ten occupations for work-related musculoskeletal disorders, with incident rates of 8.8 per 100 in hospital settings and 13.5 in nursing home settings.[1]

The bill requires that nursing homes and hospitals develop a program to adopt and implement safe patient handling and moving practices. The program requirements include:

- Establishment of a safe patient handling and moving committee to implement a minimal lift program in the facility;
- Education of staff on back injuries;
- Acquisition of equipment that aids lifting; and
- Development of procedures that allow a nurse to refuse patient handling because the nurse believes it will result in injury.

The bill authorizes the Agency for Health Care Administration to develop rules to require compliance by January 1, 2007.

According to the Agency for Health Care Administration (AHCA) the total expenditures for the first year will be $65,269 and $62,659 for the second year.

The effective date of the bill is July 1, 2006.

[1] 2002.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill increases the Agency for Health Care Administration's regulatory oversight of safe patient handling and lifting practices in nursing homes and hospitals. The estimated fiscal impact of the bill is $65,269 in the first year and $62,659 in the second year.

B. EFFECT OF PROPOSED CHANGES:

HB 1177 creates s. 381.029, F.S., to require hospitals and nursing homes to develop a program to adopt and implement safe patient handling and moving practices. The program requires hospitals and nursing homes to:

- Establish a safe patient handling and moving committee to implement a minimal lifting program in the facility;
- Analyze the risk of injury to patients and staff posed by handling and moving of patients and the physical environment in which the moving occurs;
- Educate staff on back injuries and alternative ways to reduce risks;
- Establish a program that eliminates manual lifting;
- Acquire equipment that aids lifting;
- Develop procedures that allow a nurse to refuse a patient handling or moving task because the nurse believes he or she will pose the patient or themselves to an unacceptable risk of injury; and
- Report annually to the governing body of the facility on the identification, assessment, and development of strategies to control risk of injury to patients and staff associated with the program.

The bill also requires facilities to publish their lift policy and plan, and the results of an annual evaluation that uses data analysis to measure the success of the program. The policy must be submitted to the Agency for Health Care Administration (AHCA).

The bill requires that a hospital or nursing home may not penalize, discriminate against, or retaliate in any manner against an employee if such employee reports a suspected violation, participates in an investigation, or discusses suspected violations with any other employee, patient or public.

The bill authorizes AHCA to develop rules to require compliance with the bill by January 1, 2007.

The effective date of the bill is July 1, 2006.

CURRENT SITUATION

Hospitals licensed under ch. 395, F.S., have requirements for nursing services, functional safety, and plans submission. Section 59A-3.2085(5)(d), Florida Administrative Code (F.A.C.) requires that each hospital must develop written standards of nursing practice and related policies and procedures to define and describe the scope and conduct of patient care provided by the nursing staff.

Currently there are no requirements for specific policies and procedures for patient handling and moving in hospitals. Section 59A-3.277, F.A.C., requires each hospital to have a hospital safety committee to adopt, implement and monitor a comprehensive, hospital-wide safety program. The program must adopt written policies and procedures to enhance the safety of the hospital, its personnel and patients.

Section 59A-3.080, F.A.C., states that no construction work, including demolition, shall be started until written approval has been given by the Agency's Office of Plans and Construction. This includes all construction of new facilities and any and all additions, modifications or renovations to existing facilities. Presently, any remodeling plans for the purpose of incorporating patient handling and moving equipment would have to be submitted to the Office of Plans and Construction for approval.

Currently, most hospitals and nursing homes have voluntarily adopted additional programming to prevent injury to personnel who move patients. Hospitals and nursing homes are responsible for paying worker's compensation claims and paying for temporary help when staff is unavailable because of injury.

BACKGROUND

Health Care Injury

According to the Bureau of Labor Statistics nursing personnel are consistently listed as one of the top ten occupations for work-related musculoskeletal disorders, with incident rates of 8.8 per 100 in hospital settings and 13.5 per 100 in nursing home settings.[2] The Occupational Safety and Health Administration (OSHA) reports that most health care industries report more injuries than other high risk industries, such as construction. Nursing aides, orderlies, and attendants have a risk of lost workday injuries and illnesses about 3.5 times that of the average private industry worker. The most common injury is various forms of back injury. The U.S. Department of Labor reports that nursing, psychiatric, and home health aides are especially susceptible to lifting injuries, because mechanical lifting devices available in some institutional settings are seldom available in the home care setting.

The National Institute for Occupational Safety and Health (NIOSH) is currently developing safe patient handling and movement principles. NIOSH, Centers for Disease Control (CDC) and many other national organizations have developed a model for protecting the safety and health of health care workers.

Challenges to Patient Lifting

Patient handling and movement tasks are physically demanding, performed under unfavorable conditions, and are often unpredictable in nature. Patients offer multiple challenges including variation in size, physical disabilities, cognitive function, level of cooperation, and fluctuations in condition. As a load to be lifted, patients lack the convenience of handles and even distribution of weight, and have been known to be combative during the lifting process. One study has estimated that the cumulative weight lifted by a nurse in a typical 8-hour shirt is equivalent to 1.8 tons.[3] Lifting patients is also challenging because patient lifts are often accomplished in awkward positions such as bending or reaching over beds or chairs while a nurse's back is flexed.[4]

Costs of Back Injury

Back injury can result in days away from work, expensive rehabilitation costs, surgery, and a change in career. The estimated cost to treat a back strain is $4,000 and back surgery costs around $25,000. Indirect costs related to lost production, retraining, and sick or administration time is estimated to be at least four times that of direct costs.[5]

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[2] 2002.
[3] Tuohy-Main, K. (1997) Why manual handling should be eliminated for resident and career safety. Geriaction, 15, 10-14.
[4] Blue, C.L. (1996). Preventing back injury among nurses. Orthopaedic Nursing, 15, 9-22., & Videman, T., Nurminen, T., Tolas, S., Juorinka, I., Vanharanta, H., & Troup, J. (1984). Low back pain in nurses and some loading factors of work. Spine, 9(4), 400-404.
[5] Occupational Safety and Health Administration, 1999.

Patient Moving Legislation in other States

States have begun to pass legislation regarding patient handling in hospitals and nursing homes. Last July, Texas was the first state in the nation to require hospitals and nursing homes to implement safe patient handling and movement programs. California, Massachusetts, and New York are considering bills that address patient handling in differing ways. Ohio recently created a program that provides nursing homes interest free loans to implement a no-manual-lift program. Most recently Washington passed a law similar to HB 1177. The Washington bill provides a tax credit for hospitals to comply with the law, which is not included in HB 1177. The maximum tax credit for each hospital is $1,000 for each acute care inpatient bed.[6]

C. SECTION DIRECTORY:

Section 1. – Creates s. 381.029, F.S., to require hospitals and nursing home governing bodies to create and implement a program to decrease injury to nurses and patients.

Section 2. – The effective date of the bill is July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

FISCAL IMPACT ON AHCA/FUNDS:

	FTE	Amount Year 1 FY 06-07	Amount Year 2 FY 07-08
Expenditures:			
Health Services & Facilities Consultant			
Total Salary and Benefits	1.0	$51,326	$51,326
Expenses			
Professional Staff	1.0		
Total Expenses		$10,940	$10,940
Human Resources Services			
Total Human Resources Services		$393	$393
Total Recurring Expenditures	**1.0**	**$62,659**	**$62,659**
Sub-Total Non-Recurring Expenditures		$2,610	$0
Sub-Total Recurring Expenditures		$62,659	$62,659
Total Expenditures	**1.0**	**$65,269**	**$62,659**

[6] House Bill 1672 passed the Washington Legislature March 7, 2006.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Nursing homes and hospitals will incur costs to implement the provisions in the bill. It is possible that the affected facilities may pass on the costs to their patients. The provisions in the bill may decrease back injuries in nursing homes and hospitals, thus, decreasing workers compensation payments and decreasing costs related to time away from work due to injury.

D. FISCAL COMMENTS:

According to the Agency for Health Care Administration (AHCA), one Health Services and Facilities Consultant, Pay Grade 24, full time employee (FTE) would be needed by AHCA for rule promulgation, setting up a format for the annual reports, collecting the reports, reviewing the reports, and entering the data into a format for internal reports or for the public. The total expenditures for FY 06-07, including salary, benefits, and taxes, will be $65,269 and $62,659 for FY 07-08.

According to AHCA, the proposed bill implies that AHCA may get complaints about violations of the requirements so there may be a potential increase in complaints and investigations affecting the Complaint Administration Unit and the field offices of the Division of Health Quality Assurance in the Agency, as well as the Office of the General Counsel.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides rulemaking authority to the Agency for Health Care Administration (AHCA) to carry out the provisions in the bill. However, ch. 381, F.S., is not a licensing statute for nursing homes or hospitals and AHCA may not be able to promulgate rules or enforce the bill. The bill should reference hospital and nursing home licensing statutes chapters 395 and 400, part II, F.S. respectively.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill references "nurses" several times in the bill, however, nurses are not the only staff who handle and lift patients. Nursing aides and orderlies do the majority of patient lifting. The scope of staff included in the bill also should be expanded to include all staff involved in lifting and moving patients.

[See B. RULE-MAKING AUTHORITY]

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to patient handling and moving practices; creating s. 381.029, F.S.; providing definitions; requiring hospitals and nursing homes to adopt and implement a safe patient handling and moving policy and providing requirements thereof; requiring establishment of a safe patient handling and moving committee; providing for the incorporation of patient handling and moving equipment into certain architectural plans for construction or remodeling of a hospital or nursing home or units thereof; requiring the submission of policies and remodeling plans to the Agency for Health Care Administration; providing certain protection for employees of hospitals and nursing homes who report certain violations or suspected violations; providing rulemaking authority to the agency; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.029, Florida Statutes, is created to read:

381.029 Safe patient handling and moving practices.--

(1) As used in this section:

(a) "Agency" means the Agency for Health Care Administration.

(b) "Good faith" means that an employee believes that the information he or she reported or disclosed is true and that a violation has occurred or may occur.

(c) "Hospital" means a facility licensed under chapter 395.

(d) "Minimal-lift philosophy" means to the greatest extent possible minimizing lifting tasks, encouraging a patient to assist with any lifting or moving activities without exacerbating his or her condition or putting himself or herself at risk, and avoiding any handling that involves manually lifting or moving the whole or a large part of a patient's weight.

(e) "Nurse" means a registered nurse, a licensed practical nurse, or an advanced registered nurse practitioner as those terms are defined in s. 464.003.

(f) "Nursing home" means a facility licensed under part II of chapter 400.

(2)(a) The governing body of a hospital or nursing home shall adopt and ensure implementation of a policy and program to identify, develop, and assess strategies to control the risk of injury to patients and nurses associated with lifting, transferring, repositioning, or moving a patient.

(b) The policy shall be consistent with a minimal-lift philosophy and establish a process that, at a minimum, includes:

1. Establishment of a safe patient handling and moving committee with the responsibility of implementing a minimal manual lift program in the facility. The committee may be a subcommittee of any already existing committee and shall include in its membership representatives of the bargaining unit, where one is recognized, and members of the nursing staff from various units of the facility.

2. Analysis of the risk of injury to patients, nurses, and health care workers posed by the handling and moving needs of the patient populations served by the hospital or nursing home and the physical environment in which patient handling and moving occurs.

3. Education of a back injury resource nurse to serve as an expert resource and educational source for all nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling and moving.

4. Evaluation of alternative ways to reduce risks associated with patient handling and moving, including evaluation of equipment and the environment.

5. Establishment of a program that will eliminate manual lifting, repositioning, and moving of patients based on current research and practice.

6. Acquisition of, training with, and deployment of sufficient equipment and aids so that manual lifting, repositioning, or moving all or most of a patient's weight is restricted to emergency, life-threatening, or otherwise exceptional circumstances.

7. Collaboration between the staffing committee and the nurse and the submission of an annual report to the committee.

8. Procedures that a nurse may employ to refuse to perform or be involved in patient handling or moving that the nurse believes in good faith will expose the patient or the nurse to an unacceptable risk of injury.

9. Submission of an annual report to the governing body of the hospital or nursing home and the agency on activities

related to the identification, assessment, and development of strategies to control risk of injury to patients, nurses, and other health care workers associated with lifting, transferring, repositioning, or moving a patient.

10. Publication of the policy and plan for implementation of the program and of the results of an annual evaluation that uses data analysis to measure the success of the program.

(3) The feasibility of incorporating patient handling and moving equipment or the physical space and construction design needed to incorporate that equipment at a later date shall be considered in the development of architectural plans for constructing or remodeling a hospital or nursing home or a unit of a hospital or nursing home in which patient handling and moving occurs. The hospital or nursing home shall submit its policy and any plans for remodeling to the agency.

(4) A hospital or nursing home may not penalize, discriminate against, or retaliate in any manner against an employee with respect to compensation for, or terms, conditions, or privileges of, employment if such an employee in good faith, individually or in conjunction with another person or persons:

(a) Reports a violation or suspected violation of this section to a regulatory agency, private accrediting body, or management personnel of the hospital or nursing home;

(b) Initiates, cooperates in, or otherwise participates in an investigation or proceeding brought by a regulatory agency or private accrediting body concerning matters covered by this section;

(c) Informs or discusses with any other employee, with any representative of an employee, with a patient or patient representative, or with the public violations or suspected violations of this section; or

(d) Otherwise avails himself or herself of the rights set forth in this section.

(5) The agency shall develop rules for administering this act that require compliance with policy development and reporting by January 1, 2007, and full implementation of safe handling and moving policies by July 1, 2007.

Section 2. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 38-40 and insert:

(e) "Nursing staff" means nurses licensed pursuant to part I of chapter 464, certified nursing assistants certified pursuant to part II of chapter 464, and any other staff designated by the governing body of a hospital or quality assurance committee of a nursing home, involved in the handling, lifting, and moving of patients.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 2 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 43 and insert:

(2)(a) The governing body of a hospital or quality assurance committee of a nursing home

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 3 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 46-81 and insert:

injury to patients and nursing staff associated with lifting, transferring, repositioning, or moving a patient.

(b) The policy shall be consistent with a minimal-lift philosophy and establish a process that, at a minimum, includes:

1. Establishment of a safe patient handling and moving committee with the responsibility of implementing a minimal manual lift program in the facility. The committee may be a subcommittee of any already existing committee and shall include in its membership representatives of the bargaining unit, where one is recognized, and members of the nursing staff from various units of the facility.

2. Analysis of the risk of injury to patients, nurses, and health care workers posed by the handling and moving needs of the patient populations served by the hospital or nursing home and the physical environment in which patient handling and moving occurs.

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3. Education of a back injury resource nurse to serve as an expert resource and educational source for all nurses in the identification, assessment, and control of risks of injury to patients and nursing staff during patient handling and moving.

4. Evaluation of alternative ways to reduce risks associated with patient handling and moving, including evaluation of equipment and the environment.

5. Establishment of a program that will eliminate manual lifting, repositioning, and moving of patients based on current research and practice.

6. Acquisition of, training with, and deployment of sufficient equipment and aids so that manual lifting, repositioning, or moving all or most of a patient's weight is restricted to emergency, life-threatening, or otherwise exceptional circumstances.

7. Collaboration between the staffing committee and the nurse and the submission of an annual report to the committee.

8. Procedures that nursing staff may employ to refuse to perform or be involved in patient handling or moving that the nursing staff believes in good faith will expose the patient or the nursing staff to

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 4 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 84 and insert:

the hospital or quality assurance committee of a nursing home on activities

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 5 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 118-121 and insert:

(5) The agency shall develop rules for administering this act that require compliance with policy development by January 1, 2007, and full implementation of safe handling and moving policies by July 1, 2007. The agency shall enforce the requirements of this section under its authority to regulate hospitals and nursing homes pursuant to chapter 395, and part II of chapter 400 respectively.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 6 (for drafter's use only)

Bill No. **HB 1177**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation Committee

Representative(s) Roberson offered the following:

Amendment (with directory and title amendments)

Remove line(s) 121 and insert:

handling and moving policies by July 1, 2010.

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1397 Drug Distribution
SPONSOR(S): Homan
TIED BILLS: **IDEN./SIM. BILLS:** HB 685 CS, CS/SB 1540

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell AB	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 1397 addresses pedigree paper requirements that were implemented as part of the 2003, SB 2312 reform of the Florida Drug and Cosmetic Act. The reform was in response to the Seventeenth Statewide Grand Jury[1] and the 2003 OPPAGA report[2] on drug fraud and diversion.

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug. According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900[3] out-of-state wholesalers.

The 2003 reforms in SB 2312 currently provide for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II is set to be implemented July 1, 2006. The purpose of the bill is to provide an alternative to the full pedigree paper requirements set to be implemented in phase II.

The alternative to the pedigree paper requirements in the bill provide that, until December 31, 2008, each person involved in the wholesale distribution of prescription drugs may provide a statement, in electronic form, stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer and is an "authorized distributor of record" in lieu of a pedigree paper as defined in s. 499.003(31), F.S.

HB 1397 also establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit." The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state to veterinarians, of veterinarian prescription drugs and prescription drugs regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.[4] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The Department of Health estimates that, with the creation of the limited veterinary wholesaler permit, there will be a yearly loss of $3,000 that will have no effect on current operations.

The effective date of the bill is July 1, 2006.

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[1] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[2] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.
[3] According to the Department of Health 2003 records.
[4] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government - HB 1397 creates a new prescription drug wholesaler permit, the limited prescription drug veterinary wholesaler permit. The new permit would allow veterinary wholesalers to provide legend drugs intended for human use but limits the sales to no more than 30 percent. The bill decreases requirements for veterinary wholesalers that wish to provide legend drugs intended for human use. The Department of Health estimates a yearly loss of $3,000 of regulatory fees with the creation of the limited veterinary wholesaler permit.

B. EFFECT OF PROPOSED CHANGES:

CURRENT SITUATION – PEDIGREE PAPERS

The 2003 Legislature passed comprehensive reforms to the Florida Drug and Cosmetic Act to address drug fraud and diversion. The law currently provides for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II, full pedigree paper requirements, is set to be implemented July 1, 2006.

Currently there are two different record keeping requirements for prescription drugs in Florida. If a prescription drug is on the specified drug list wholesalers must follow one set of requirements, and if a prescription drug not listed on the "specified drug list" another set of requirements must be followed.

According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900[5] out-of-state wholesalers, of which less than ten percent are one of the three large full-line wholesalers or their distribution centers, or major full-line regional wholesalers. The remainders are secondary wholesalers that primarily buy and sell among other prescription drug wholesalers rather than to end-users such as hospitals or other health care entities, including physicians or pharmacies.

Pedigree Requirements for "Specified Drugs"

The Department of Health (DOH) determines "specified drugs" by rule. DOH publishes a "specified drug list" on their website. Specified drugs are the drugs most likely to be adulterated. There are currently 34 drugs on the "specified drug list."

There are three different regulatory options when engaged in the wholesale distribution of a specified drug. Each person who is engaged in the wholesale distribution of a specified drug must provide each wholesale distributor, upon any sale, a written statement that :

1. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or
2. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or
3. Before the wholesale distribution (sale of the prescription drug), a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and a sales invoice number of the invoice evidencing each specific unit of the specified drug.

[5] According to the Department of Health 2003 records.

Pedigree Requirements for drugs not list on the "Specified Drug List"

Wholesalers, who do not qualify as an "authorized distributor of record (see below)" purchasing prescription drugs not listed on the "specified drug list," must provide a pedigree paper, under oath, that traces the prescription drug back to the last authorized distributor of record (rather than back to the manufacturer of the drug).

"Authorized Distributor of Record"

Authorized Distributor of Record (ADR) is defined by s. 499.0121, F.S., as a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship exists when a wholesale distributor (including an affiliated group) meets the following requirements:

- Is listed on the manufacturer's current list of authorized distributors of record;
- Annually purchases at least 90 percent of all its prescription drugs directly from one manufacturer and has at least $100 million in total annual prescription drug sales;
- Makes at least 12 yearly purchases from the wholesale distributor; and
- Meets Department of Health (DOH) reporting requirements.

Pursuant to s. 499.0121, F.S., DOH publishes a list of wholesale distributors that qualify as an authorized distributor of record. Currently, there are 525 wholesalers listed.[6] Currently, each person engaged in wholesale distribution who does not meet ADR specification must prepare and provide a pedigree paper for the distribution of a prescription drug (not listed on the "specified drug list"[7]) back to the last ADR (rather than back to the manufacturer of the drug). ADR wholesalers do not have to meet this provision.

"Affiliated Group" Designation

Affiliated groups are defined by s. 1504 of the Internal Revenue Code of 1986. According to s. 499.0121, F.S., "affiliated groups" are composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers. Affiliated groups must:

- Disclose to the Department of Health (DOH) the names of all the members; and
- Agree in writing to provide records on prescription drug purchases by members of the same affiliated group not later than 48 hours after DOH requests such records, regardless of where the records are stored.

Warehouses within the affiliated group must comply with all federal and state wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs to only a retail pharmacy or warehouse within the affiliated group. Prescription drug wholesalers within an affiliated group are exempt from pedigree paper requirements as long as the drugs do not leave the affiliated group. The Department of Health may request all records related to purchase or acquisition of prescription drugs, and the affiliated group must make them available.

The affiliated group designation was scheduled to sunset July 1, 2006. However, the 2005 Legislature removed the sunset provision, thus during phase II of the pedigree paper reforms the affiliated group exemption will continue indefinitely.

Pedigree Papers Requirements

Currently, on July 1, 2006 the special provisions for "authorized distributor of record" will phase out and all players will be required to meet the same pedigree paper requirements.

On July 1, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug, must provide a pedigree paper defined in s. 499.003(31), F.S., to the person who receives the drug.

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[6] See Department of Health Website, http://www.doh.state.fl.us/pharmacy/drugs/index.html

[7] The specified drug list is a list of prescription drugs that are most likely to be diverted. The Department of Health places drugs that meet certain requirements on the list. There are currently 34 drugs on the specified drug list.

The Department of Health (DOH) is currently in final stages of the rule-development process regarding pedigree papers, including provisions for digital pedigree papers. The next rule hearing is scheduled for April 3, 2006. Recently, DOH sent out a letter to all companies that currently have an active permit to distribute wholesale prescription drugs in Florida to remind them of the full implementation of pedigree papers July 1, 2006.

During the 2005 Legislative Session, the definition of pedigree paper was amended to clarify that a pedigree paper may be in either paper or electronic form.[8] A pedigree paper must include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.

Pedigree Papers Implementation Process

Phase I	Phase II	Proposed Legislation
Specified Drug List Pedigree *Three Options:* 1. May buy drug directly from manufacturer (no pedigree); 2. May buy drug in a closed affiliated group system; or 3. Provide a pedigree that tracks drug back to the manufacture of the drug (including lot number, invoice number, etc.). **Drugs not listed on the Specified Drug List Pedigree** Requires a pedigree that traces the prescription drug back to the last "authorized distributor of record." **Authorized Distributor of Record** Defined in statute[9] as a wholesale distributor with whom a manufacturer has established an ongoing relationship. Must meet certain criteria. **Affiliated Group Designation** Defined in statute[10] as chain drug entities that include at least 50 retail pharmacies, warehouses, and repackagers. Must meet certain criteria. May sell prescription drugs within their affiliated group without passing a pedigree paper (must provide one to the Department of Health if requested). Must pass a pedigree if selling drugs to individuals not in their affiliated group.	**All Prescription Drugs** All persons engaged in the wholesale distribution of a prescription drug must pass a pedigree paper (lot number, invoice, etc.) for all drugs. **Special provisions for "affiliated groups" still apply (see phase I).**	**All Prescription Drugs** All persons engaged in the wholesale distribution of a prescription drug must pass a pedigree paper (lot number, invoice, etc.) for all drugs. **OR** **All Prescription Drugs** Until December 31, 2008, may purchase drugs without passing a pedigree if the drug was purchased directly from the manufacturer and is an "authorized distributor of record (see phase I)." **Special provisions for "affiliated groups" still apply (see phase I).**

[8] Section 499.003(31, Florida Statutes.
[9] Section 499.0121, Florida Statutes.
[10] Section 499.0121, Florida Statutes.

EFFECT OF THE PROPOSED CHANGES – PEDIGREE PAPERS

HB 1397 creates an alternative to implementation of full pedigree paper requirements July 1, 2006.

The bill provides that, until December 31, 2008, each person involved in the wholesale distribution of prescription drugs may provide a statement, in electronic form, stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer and is an "authorized distributor of record" in lieu of a pedigree paper as defined in s. 499.003(31), F.S. The bill continues the Department of Health's publication of "authorized distributors of record" on its website.

The effective date of the bill is July 1, 2006.

CURRENT SITUATION - VETERINARIAN WHOLESALER PERMIT

Veterinary Prescription Drug Wholesaler Permits

Section 499.01, F.S., requires a permit for any person or establishment that wishes to operate as a veterinary prescription drug wholesaler. Veterinary prescription drug wholesaler is defined as any person engaged in the wholesale distribution of veterinary prescription drugs in or into Florida.[11] Veterinarian wholesalers may *only* sell drugs manufactured for animal use. If a veterinarian wholesaler wishes to sell *any* drugs manufactured for human use, a prescription drug wholesaler permit is required in lieu of a veterinarian prescription drug wholesaler permit.

EFFECT OF THE PROPOSED CHANGED – VETERINARIAN WHOLESALER PERMIT

Limited Prescription Drug Wholesaler Permit

HB 1397 establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit." The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state to veterinarians, of veterinarian prescription drugs and prescription drugs regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.[12] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The bill defines any human prescription drug, regulated under s. 503(b), as an adulterated drug if it has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

The bill provides that no more than 30 percent of drug sales by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements under s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., when a prescription drug is distributed wholesale to a veterinarian.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or no more than $500 annually.

The bill requires the Department of Health (DOH) to inspect each limited prescription drug wholesaler. It authorizes DOH to order immediate closures of a limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health safety and welfare.

[11] Section 499.003(40), Florida Statutes.
[12] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

The Department of Health estimates that, with the creation of the limited veterinary wholesaler permit, there will be a yearly loss of $3,000 that will have no effect on current operations.

Prescription Drug Wholesalers

All prescription drug wholesalers are required to post a $100,000 bond and to file an extensive permit application that includes the submission of fingerprint cards for all key individuals associated with the wholesaler's operations in order for a criminal history check to be performed. In addition, each prescription drug wholesaler must have a designated representative who has successfully passed an examination on federal and state laws, and department rules, relating to the wholesale distribution of prescription drugs.

	Prescription Drug Wholesaler	Limited Veterinarian Prescription Drug Wholesaler (proposed permit)	Veterinarian Prescription Drug Wholesaler
Type of Prescription Drugs Dispensed	Legend drugs defined or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.	May dispense up to 30% of sales from legend drugs.	Veterinarian legend drugs only.
Required Deposit	$100,000 bond, certificate of deposit, or letter of credit	$20,000 bond, certificate of deposit, or letter of credit	None required.
Authorized yearly fees	$800 Annually s. 499.041(2)(a), F.S.	$300-$500 Annually (proposed legislation)	$500 s. 499.041(g), F.S.

BACKGROUND

Pedigree Papers

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and should contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug.

Seventeenth Statewide Grand Jury Report[13]

The Seventeenth Statewide Grand Jury report[14] released by the Office of the Attorney General, February 28, 2003, found "an alarming percentage of drugs flowing through the wholesale market have been illegally acquired" via theft from pharmacies and hospitals; purchases on the black market by individuals defrauding insurance companies and Medicaid; or illegal importation. Despite a 1993 state law that requires drugs to have documentation showing all the hands they passed through on the way to the patient, the investigative panel found that neither this law nor an updated version in 1996 has ever been fully enforced, in part due to industry objections.

Office of Program Policy Analysis and Government Accountability (OPPAGA) Report[15]

In February, 2003, the OPPAGA issued report No. 03-18 highlighting problems with counterfeit and diverted drugs in Florida. The findings of the report indicated that millions of dollars are lost due to counterfeit and diverted drugs in Florida's prescription drug wholesale industry. The report found a rise in drug cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concluded that current Florida law did not provide adequate controls over wholesale drug market practices, and current administrative and criminal penalties failed to provide an adequate deterrent.

[13] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[14] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[15] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

Florida Drug & Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, pt. 1, ch. 499, F.S., the Department of Health is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics. Wholesalers, manufacturers, and distributors of drugs or devices must be permitted by the department or otherwise exempt.[16]

Under the Florida Drug and Cosmetic Act (or the Act), any person who is at least 18 years of age or older and who can pay the permit fee, and after submission of specified information that all permit applicants must provide, with certain exceptions, may obtain a permit as a prescription drug wholesaler.[17] The applicant must not have been found guilty, regardless of adjudication, of a violation of a law that directly relates to a drug, device, or cosmetic. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler distributor located outside of Florida must be permitted by the Department of Health. The department is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state that has requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its laws to a Florida-permitted drug wholesaler.

The Florida Drug and Cosmetic Act specifies criminal penalties for violations relating to activities regulated by the department under the Act. Such criminal offenses are, with few exceptions, punishable as a second-degree misdemeanor (a maximum fine of $1,000 or 1 year imprisonment) if it is a second conviction for the violation of the Act.

The Act requires prescription drug wholesalers to maintain records that provide a complete audit trail of prescription drugs from purchase to sale or other disposition. Such records known as "pedigree papers" must include a written statement of all previous sales of the drug that is sold in a wholesale market.

SB 2312: 2003 Reform of Florida Drug and Cosmetic Act (the Act)

In 2003 the Legislature revised the Florida Drug and Cosmetic Act to impose more stringent regulation on prescription drug wholesalers.

SB 2312 adopted many of the recommendations of the Seventeenth Statewide Grand Jury report[18] and OPPAGA report[19] on drug diversion. The bill significantly strengthened record keeping requirements for wholesalers and repackagers of prescription drugs. Several of these new "pedigree paper" requirements have a second phase-in period starting July 1, 2006.

The bill created criminal offenses relating to illicit activities involving diversion from wholesale distribution of prescription drugs. Additional prohibitions were created regarding label tampering with the intent to distribute a drug and the distribution of a drug previously dispensed by a Florida-licensed pharmacy. Effective January 1, 2004, the permitting requirements for drug wholesalers were overhauled to require extensive information upon application for a permit, including a criminal history background check, and to require that permits expire annually rather than biennially.

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[16] Drug marketing is also subject to regulation under the Federal Prescription Drug Marketing Act of 1987 which establishes minimum standards for the prescription drug industry that include requirements for an audit trail of sales transactions.

[17] See ss. 499.01 and 499.012, F.S. The permitting requirements for a number of establishments licensed or permitted by the Department of Health to engage in activities regulated under the Florida Drug and Cosmetic Act are the same. Such establishments include: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

[18] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.

[19] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

Track and Trace Technology

According to the U.S. Food and Drug Administration (FDA), it is critical to implement new technologies to better protect the drug supply. In a recent report the FDA concluded, that a combination of rapidly improving track and trace technologies and product authentication technologies could be used to provide a greater level of security for drug products. The FDA has stated that the adoption and wide-spread use of reliable track and trace technology is feasible by 2007.[20]

Track and trace technology refers to many technologies used to track prescription drugs through the supply chain. Two of the most notable technologies are radio-frequency identification (RFID) in combination with an electronic product code (EPC). RFID technology uses a tiny radio frequency chip containing essential data in the form of an electronic product code (EPC).[21] RFID technology is used to tag, identify, and track individual items as they move through the supply chain and into the hands of the buyer or consumer. As the objects move through the supply chain wireless RFID readers can communicate with an RFID tag on the object, collect information about the object (such as a unique number) and match that number in a database to access a complete record about the object. With RFID, product tracking occurs automatically, without the scanning of barcodes.[22] This real-time technology provides speed and accuracy in the supply chain.[23] EPC technology makes it possible to mass serialize all drug products, ensuring each is individually identified and tracked. The FDA continues to play an active role in public and private sector efforts towards developing an "electronic safety net" for our drug supply.[24]

The FDA recognizes that states have implemented and are considering provisions that require a pedigree (in some cases electronic) for drug products. The FDA supports these efforts because they complement federal requirements. Further, the FDA believes that rapid and uniform implementation of a pedigree that starts at the point of manufacture and accompanies the drug product until it is dispensed would be beneficial.[25]

C. SECTION DIRECTORY:

Section 1. – Amends s. 499.006, F.S., to define a prescription drug returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug. Prescription drugs are those regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

Section 2. – Amends s. 499.01, F.S., to require a permit for any person or establishment that intends to operate as a limited prescription drug veterinary wholesaler. The bill provides that the limited drug veterinary wholesaler permit may not be issued to the address of a health care entity or pharmacy licensed under ch. 465, F.S., except as provided in s. 499.01(2)(d), F.S.

Section 3. – Amends s. 499.012, F.S., to establish a limited prescription drug veterinary wholesaler permit. The bill provides several permit requirements and conditions under the permit, including a $20,000 bond or equivalent surety requirement, and provides permissible transactions under the permit.

Section 4. – Amends s. 499.0121, F.S., to provide an alternative to full pedigree paper requirements set to implement July 1, 2006.

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[20] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[21] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[22] Electronic Pedigree for Pharmaceuticals, SupplyScape, 2005.
[23] RFID Technology and EPC in Retail, Symbol, 2004.
[24] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[25] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.

Section 5. – Amends s. 499.01221(1)(d) F.S., to delete veterinarians from the group of persons or entities to whom a veterinary legend drug retail establishment may sell veterinary legend drugs. The bill would permit a veterinary legend drug retail establishment to only sell veterinary legend drugs to the public.

Section 6. – Amends s. 499.041, F.S., to require a fee for a limited prescription drug veterinary wholesaler's permit. The bill provides the fee may not be less than $300 or more than $500 annually.

Section 7. – Amends s. 499.065, F.S., to require the Department of Health (DOH) to inspect each limited prescription drug veterinary wholesaler. The bill permits DOH to order the immediate closure of limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health, safety, or welfare.

Section 8. – Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Department of Health Estimates - Limited Prescription Drug Wholesaler Permit

Estimated Revenue	**1st Year**	**2nd Year** (Annualized/Recurr.)
Decrease in permit fee revenue $300 for est. 10 permits	-3,000	-3,000
Total Estimated Revenue	- $3,000	- $3,000

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Alternative to Pedigree Paper Requirements

Proponents of the bill report that implementation of full pedigree paper requirements, without radio frequency identification (RFID), will be a burden to the pharmaceutical industry that will increase the cost of prescription drugs.

Limited Veterinarian Wholesaler Permit

Under the proposed legislation, veterinary wholesalers who wish to offer some legend drugs intended for human use would have the option of obtaining a limited veterinary prescription drug wholesaler permit instead of a prescription drug wholesaler permit. Because the limited veterinary prescription drug wholesaler has fewer requirements than the prescription drug wholesaler permit, some cost savings may be realized. Wholesalers who choose to obtain the newly created permit may pass on their savings to their customers.

D. FISCAL COMMENTS:

Alternative Pedigree Paper Requirements

A fiscal analysis was requested from the Department of Health (DOH), but was not received before this analysis was published. Any information received from DOH will be included in an updated analysis.

Limited Veterinarian Wholesaler Permit

The Department of Health (DOH) estimates that no more that 10 establishments would apply and qualify to become a limited veterinarian wholesaler. As a result, the impact, assuming each is currently permitted as a prescription drug wholesaler or out-of-state prescription drug wholesaler, would be a decrease in revenue of $3,000 annually. According to DOH the $3,000 loss in revenue will have no effect on operations.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Department of Health has the necessary rulemaking authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Pedigree Paper Requirements

Proponents of the bill argue that the phase II pedigree paper requirements set to implement on July 1, 2006 will be burdensome for the industry and may increase the cost of prescription drugs. They also argue that it does not make sense to implement full pedigree paper requirements before the advent of radio frequency identification technology (RFID).

Opponents assert that the phase II regulations will provide added safety to the Florida prescription drug supply. They also argue that requiring pedigree papers for all prescription drug transactions will increase transparency and drive drug diverters out of the market. Opponents feel that full pedigree paper requirements are needed to address the concerns raised in the Seventeenth Statewide Grand Jury report[26] and OPPAGA report on drug diversion.

[26] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to drug distribution; amending s. 499.006, F.S.; providing that a drug is adulterated if it is a certain prescription drug that has been returned by a veterinarian to a limited prescription drug veterinary wholesaler; amending s. 499.01, F.S.; requiring a limited prescription drug veterinary wholesaler to obtain a permit for operation from the Department of Health; providing that a permit for a limited prescription drug veterinary wholesaler may not be issued to the address of certain health care entities; amending s. 499.012, F.S.; revising permit requirements for a veterinary prescription drug wholesaler that distributes prescription drugs; establishing a permit for a limited prescription drug veterinary wholesaler; providing requirements; providing an exception; amending s. 499.0121, F.S.; removing an expiration date on a provision relating to prescription drug recordkeeping; requiring certain information to be provided by certain prescription drug wholesalers to drug recipients; requiring drug manufacturers to file a list of authorized distributors with the department; requiring the department to publish certain information; amending s. 499.0122, F.S.; redefining the term "veterinary legend drug retail establishment"; amending s. 499.041, F.S.; requiring the department to assess an annual fee within a certain monetary range for a limited prescription drug veterinary wholesaler permit; amending s. 499.065, F.S.; requiring the department to inspect each limited

prescription drug veterinary wholesaler establishment; authorizing the department to determine that a limited prescription drug veterinary wholesaler establishment is an imminent danger to the public; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.--A drug or device is adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of ss. 499.001-499.081 and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5) If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6) If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8) If it is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or

in part;

(9) If it is a drug or device for which the expiration date has passed; ~~or~~

(10) If it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of ss. 499.001-499.081 or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or~~.~~

(11) If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

Section 2. Subsection (1) and paragraph (d) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits; applications; renewal; general requirements.--

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) An over-the-counter drug manufacturer;

(d) A compressed medical gas manufacturer;

(e) A device manufacturer;

(f) A cosmetic manufacturer;

(g) A prescription drug wholesaler;

(h) A veterinary prescription drug wholesaler;

(i) A compressed medical gas wholesaler;

(j) An out-of-state prescription drug wholesaler;

(k) A nonresident prescription drug manufacturer;

(l) A freight forwarder;

(m) A retail pharmacy drug wholesaler;

(n) A veterinary legend drug retail establishment;

(o) A medical oxygen retail establishment;

(p) A complimentary drug distributor; ~~or~~

(q) A restricted prescription drug distributor; or~~.~~

(r) A limited prescription drug veterinary wholesaler.

(2)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesaler, limited prescription drug veterinary wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesaler permit to the address of a community

pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

Section 3. Paragraph (g) of subsection (2) of section 499.012, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

499.012 Wholesale distribution; definitions; permits; applications; general requirements.--

(2) The following types of wholesaler permits are established:

(g) A veterinary prescription drug wholesaler permit.--A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler, an ~~or~~ out-of-state prescription drug wholesaler, or a limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f).

(h) Limited prescription drug veterinary wholesaler permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited prescription drug

veterinary wholesaler permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to veterinarians under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to veterinarians on a full-time basis.

2. No more than 30 percent of prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person is not permitted, licensed, or otherwise authorized in any state to wholesale prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesaler that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to

pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesaler is not required to provide a pedigree paper as required by s. 499.0121(6)(f) upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. An out-of-state prescription drug wholesaler's permit or a limited prescription drug veterinary wholesaler permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesaler in this state if

both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

Section 4. Paragraphs (d) and (f) of subsection (6) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record for the drug manufacturer's products, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement under oath identifying each previous sale of the drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement must accompany the drug to the next wholesale distributor. The department shall adopt rules relating to the requirements of this written statement. This paragraph does not apply to a

manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1. and paragraph (e).

3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

4. Each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

5. For the purposes of this subsection, the term "authorized distributors of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Effective March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

a. Is listed on the manufacturer's current list of authorized distributors of record.

b. Annually purchases not less than 90 percent of all of its purchases of a manufacturer's prescription drug products,

based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of $100 million or more.

c. Has reported to the department pursuant to s. 499.012(3)(g)2. that the wholesale distributor has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's drug products directly from the manufacturer using said verifiable account number in 12 months. The provisions of this sub-subparagraph apply with respect to a manufacturer that fails to file a copy of the manufacturer's list of authorized distributors of record with the department by July 1, 2003; that files a list of authorized distributors of record which contains fewer than 10 wholesale distributors permitted in this state, excluding the wholesale distributors described in sub-subparagraph b.; or that, as a result of changes to the list of authorized distributors of record filed with the department, has fewer than 10 wholesale distributors permitted in this state as authorized distributors of record, excluding the wholesale distributors described in sub-subparagraph b.

A wholesale distributor that satisfies the requirements of sub-subparagraph b. or sub-subparagraph c. shall submit to the department documentation substantiating its qualification pursuant to sub-subparagraph b. or sub-subparagraph c. The

department shall add those wholesale distributors that the department has determined have met the requirements of sub-subparagraph b. or sub-subparagraph c. to the list of authorized distributors of record on the department's website.

~~6. This paragraph expires July 1, 2006.~~

(f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug either:

a. A pedigree paper as defined in s. 499.003(31); or

b. Until December 31, 2008, if the prescription drug was purchased directly from the manufacturer, a statement in written or electronic form stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer, as defined in s. 499.012(1)(e), and is an authorized distributor of record as specified in subparagraph (d)5. In accordance with subparagraph (d)5., each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department by July 1, 2006. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

2. A repackager must comply with this paragraph.

3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.

4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.

5. In order to verify compliance with subparagraph (d)1., each manufacturer of a prescription drug sold in this state must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

Section 5. Paragraph (d) of subsection (1) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

(1) As used in this section, the term:

(d) "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public ~~or to veterinarians,~~ but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary legend drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary legend drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary legend drug retail establishment must sell a veterinary legend drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary legend drug.

Section 6. Paragraph (h) is added to subsection (2) of section 499.041, Florida Statutes, to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.--

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(h) The fee for a limited prescription drug veterinary wholesaler's permit may not be less than $300 or more than $500 annually.

Section 7. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Imminent danger.--

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, and retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter as often as necessary to ensure compliance with applicable laws and rules. The department shall have the

right of entry and access to these facilities at any reasonable time.

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

Section 8. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 1397**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Homan offered the following:

Amendment (with directory and title amendments)

Remove line(s) 229-345 and insert:

Section 4. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.--As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b) Effective July 1, 2006:~~,~~

1. A document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug; or~~,~~

2. A written statement under oath, that:

a. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the prescription drug directly from the manufacturer;"

b. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the prescription drug directly from the manufacturer."

The information required to be included on the form prescribed by the Department of Health pursuant to subparagraph (b)1. ~~a legend drug's pedigree paper~~ must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form prescribed by the Department of Health pursuant to subparagraph (b)1. ~~pedigree.~~ It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The department shall adopt rules and a form relating to the requirements of subparagraph (b)1. ~~this paragraph~~ no later than 90 days after the effective date of this act. Subparagraph (b)2. shall expire June 30, 2008.

Amendment No. 1 (for drafter's use only)

52

53 ========== T I T L E A M E N D M E N T ==========

54 Remove line(s) 16-22 and insert:

55

56 an exception; amending s. 499.003, F.S.; revising a

57 definition; providing an expiration date; amending

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1625 Clinical Perfusionists
SPONSOR(S): Kottkamp
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Hamrick	Mitchell
2) Business Regulation Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 1625 establishes the regulation by the Department of Health of clinical perfusionists who operate heart-lung machines used in open heart surgery.

Section 11.62, F.S., the Sunrise Act that establishes criteria for new regulation of professions, states that it is the intent of the Legislature that no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage; and no profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation. The proponents for regulation of clinical perfusionists provided adequate documentation that the public may be harmed if a clinical perfusionist is not trained appropriately. However, the proponents stated "there is no current primary source data available to correctly document the scope of public harm caused by the incompetent practice of perfusion." According to staff of the Board of Medicine, perfusionists are well-educated, allied health care professionals who assist in over 28,000 open-heart procedures annually and there have been few, if any, reports or concerns with patient safety.

Clinical perfusionists (or "perfusionists") have been recognized as a definable allied health profession by the American Medical Association since 1977. A perfusionist is responsible for the direct control, maintenance, and analysis of a patient's blood pressure, blood flow, temperature, oxygenation/carbon dioxide removal, myocardial preservation, blood and blood product administration, coagulation status, blood chemistries, equipment operation, IV fluid administration, and anesthetic drug administration. Approximately 12 states regulate perfusionists.

HB 1625 creates a regulatory scheme, provides definitions, scope of practice, and continuing education guidelines. The bill provides for the licensure of clinical perfusionists under the regulatory jurisdiction of the Board of Medicine or the Board of Osteopathic Medicine and for joint rulemaking by these boards for aspects of the practice of this profession. The bill requires a perfusionist to practice within the framework of a protocol under the supervision of a medical or osteopathic physician. The bill requires licensed perfusionists to maintain medical malpractice insurance or provide proof of financial responsibility.

Fiscal Impact: According to the Department of Health, this profession is projected to be self-sufficient due to the amount of fees a licensed perfusionist will be required to pay. An applicant may be subject to a fee no greater than $1,500 and a biannual license renewal fee no greater than $1,500. The Florida Perfusion Society, estimates that there are approximately 225 perfusionist in the state.

The bill takes effect on July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government-The bill provides for the creation of a regulatory scheme for a new profession.

B. EFFECT OF PROPOSED CHANGES:

The bill provides for the licensure of clinical perfusionists under the regulatory jurisdiction of the Board of Medicine or the Board of Osteopathic Medicine and for joint rulemaking by these boards for aspects of the practice of this profession. The regulation requires a clinical perfusionist to practice within the framework of a protocol under the supervision of a medical or osteopathic physician. The bill provides definitions and standards of practice and performance for clinical perfusionists. The Board of Medicine and the Board of Osteopathic Medicine are given rulemaking authority to implement the provisions of the bill regulating clinical perfusionists.

The bill specifies requirements for education and training of clinical perfusionists and other licensure requirements, including the expanded duties of the Board of Medicine and the Board of Osteopathic Medicine over this profession. The bill creates a criminal offense for any person who falsely holds himself or herself out as a clinical perfusionist. The bill requires the Board of Medicine and the Board of Osteopathic Medicine, by rule, to require all clinical perfusionists licensed under section 458.3476 or section 459.025, F.S., to maintain medical malpractice insurance or provide proof of financial responsibility.

CURRENT SITUATION

Clinical perfusionists (or "perfusionists") have been recognized as a definable allied health profession by the American Medical Association since 1977. Working under the direct supervision of a surgeon, perfusionists are the only non-licensed health care professionals who routinely administer drugs and blood products to patients. A perfusionist is the person responsible for the selection, set-up, and operation of a heart-lung machine. To maintain life during open-heart surgery, the patient's heart must be stopped and the patient's blood diverted outside the body, circulated through the heart-lung machine, and returned to the patient. Other procedures that a perfusionist can be involved in are plasmapheresis (a blood purification procedure used to treat several autoimmune diseases), intra-aortic balloon pumping, heart, lung and liver transplants, cardiac catheterization, and chemotherapy treatment.

According to information provided by proponents of the regulation, a perfusionist is responsible for the direct control, maintenance, and analysis of a patient's blood pressure, blood flow, temperature, oxygenation/carbon dioxide removal, myocardial preservation, blood and blood product administration, coagulation status, blood chemistries, equipment operation, IV fluid administration, and anesthetic drug administration. Approximately 12 states regulate perfusionists.[1]

Sunrise Act

Section 11.62, F.S., requires the proponents of regulation to submit information, which is structured as a sunrise questionnaire, to document that regulation meets specified criteria.

A sunrise questionnaire was submitted to staff by the proponents of the legislation to assist the Legislature in determining the need for regulation of clinical perfusionists as required by statute. The

[1] Arkansas, California, Georgia, Illinois, Louisiana, Massachusetts, Missouri, New Jersey, Oklahoma, Tennessee, Texas, and Wisconsin.

proponents for the regulation and entity responsible for submitting the sunrise questionnaire is the Florida Perfusion Society (the "proponents" or the "Society"). The Society represents certified clinical perfusionists, clinical perfusionists, and perfusion technologists. Currently, there are 115 active members, 20 associate members, and 2 life members in the Society. The Society estimates that there are approximately 225 perfusionists in the State of Florida.

According to s. 11.62(3), F.S., of the Florida Sunrise Act, the Legislature is required to consider the following factors when determining whether to regulate a profession:

- **The unregulated practice of the profession will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.**

  The proponents for regulation, provided documentation that in 1989, the number of injuries or deaths from accidents during perfusion was one per 1,000 cases performed.[2] The Society added that perfusionists rarely publish their failures and the documentation of accidents is difficult to obtain. The proponents argue that if perfusion were not a high-risk procedure, perfusionists would not be rated for malpractice insurance in a liability range equivalent to Emergency Room physicians. The proponents offered that the Wood Insurance Group (largest insurer of perfusionists in the nation), charges premiums of $5,500-$6,800 per year. The Society also noted that the heart-lung machine that is used by a perfusionist is classified by the Food and Drug Administration (FDA) as a level V medical device. This is the highest category of consumer risk for medical device products assigned by the FDA. According to the proponents, the consequences of improperly performing any of the many important tasks required of a perfusionist could result in serious patient injury or death.

  The proponents for regulation provided adequate documentation that the public may be harmed if a clinical perfusionist is not trained appropriately. However, the proponents did not submit documentation that the unregulated practice of the profession will substantially harm the public. The sunrise questionnaire states "there is no current primary source data available to correctly document the scope of public harm caused by the incompetent practice of perfusion." The proponents provided documentation from 1989, but nothing more recent.

- **The practice of the profession requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements reasonably assure initial and continuing professional ability.**

  The Society provided ample documentation that the practice of clinical perfusion requires specialized skill and training. For a certified clinical perfusionist (CCP) the skill and training is readily measurable or quantifiable. A CCP is required to perform a minimum of 40 clinical activities annually and earn 45 continuing education units (CEUs) every 3 years.

  The American Board of Cardiovascular Perfusion is the only certifying body for clinical perfusionists. They administer a two part examination. To be eligible to sit for the examination an applicant must have completed an accredited perfusionist program. There are 21 accredited programs in the US and one located in Florida. According to the provisions in the bill, to be licensed as a clinical perfusionist in Florida the applicant must attend an accredited program.

[2] Reed, Charles C. and Trudi B. Stafford. 1989. "Cardiopulmonary Bypass." 2nd edition.

- **The regulation will not unreasonably effect job creation or retention in the state, or place unreasonable restrictions on finding employment by individuals who practice or seek to practice the profession.**

  The bill requires individuals who perform clinical perfusion to become licensed. The proponents provide that there are no unregulated occupations that perform all the services of a perfusionist. The licensure fee may not exceed $1500 biannually.

- **Whether the public is not, or can not, be effectively protected by other means.**

  There are currently other mechanisms in place that protect the public. Hospitals are responsible for screening their employees and determining their competence. A clinical perfusionist functions under the supervision of a physician. The majority of perfusionists are employed by hospitals. According to the Society, the Joint Commission (JCAHO) requires employers to annually perform employee competency evaluations. Section 766.110, F.S., provides that all health care facilities in Florida, including hospitals and ambulatory surgical centers have a duty to assure comprehensive risk management and the competence of their medical staff and personnel through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties. These duties include among other specified items, a requirement to adopt written procedures for the selection of staff members and a periodic review of the medical care and treatment rendered to patients by each member of the medical staff.

  The Board of Medicine staff reports that perfusionists are well-educated, allied health care professionals who assist in over 28,000 open-heart procedures annually, with few, if any, reports of patient safety concerns. The Department of Health indicates that it is unclear to what extent the regulation of clinical perfusionist would supplant the current quality control system of hospitals and physicians.

- **Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, is favorable.**

  At this time there are no advocacy groups representing Florida consumers on this issue. According to the proponents of the regulation, the impact on consumers will remain the same, but a higher level of patient safety will be achieved. The proponents state that there will be no impact on the cost of services due to licensure since the responsibility for obtaining licensure falls on the practitioner. The licensure fee will cover all costs of regulation.

  See the "Fiscal Impact on State Government" for the Department of Health's projections on the fiscal impact.

BACKGROUND

National Organizations that Recognize Clinical Perfusionist

The American Board of Cardiovascular Perfusion (ABCP)
Established in 1975, the ABCP is an independent organization that has no organizational ties or relationships with any other group or entity. The ABCP is the primary certification body that has become the de facto standard in the field and is typically a requirement of most organizations that employ perfusionists. Individuals who become credentialed in perfusion by the ABCP must pass a certification examination to become a Certified Clinical Perfusionist (CCP). It is estimated that at least 70% of the practicing perfusionists are certified. To sit for the CCP certification examination an applicant must be a graduate of an accredited perfusion training program.

The certification examination is composed of two parts. Part I, the Perfusion Basic Science Examination, is a multiple choice examination designed to cover perfusion basic sciences and

cardiopulmonary bypass. Part II, the Clinical Applications in Perfusion Examination, is in a multiple choice format where a series of clinical scenarios are presented and a corresponding series of questions must be answered.

The CCP is conferred for a period of three years, during which time a specified number of approved continuing education credits must be earned in order to be recertified.

The ABCP website specifically states that certification "is not intended to define requirements for employment, to gain special recognition or privileges, to define the scope of extracorporeal circulation, or to state who may not engage in cardiovascular perfusion." *Further, the certification of a clinical perfusionist does not relieve an employer from determining the professional responsibilities of a cardiovascular perfusionist in his/her specific clinical setting.*[3]

The American Society of Extracorpeal Technology (AmSECT)

The American Society of Extra-Corporeal Technology was founded in 1964. AmSECT has over 2,000 members nationally and internationally. A member of AmSECT must maintain rigorous continuing education requirements.

Educational Requirements for a Clinical Perfusionist

The current level of training for clinical perfusionists is a Bachelor of Science degree or higher. Currently, there are 21 perfusionist programs in the U.S. accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). Barry University has the only accredited perfusion program in Florida and graduates about 10 students annually. As part of the clinical perfusion program at Barry University, in addition to coursework, students must perform a minimum of 75 satisfactory adult clinical bypass procedures, and perform or observe a minimum of 10 pediatric clinical bypass procedures; and satisfactorily complete a final written and clinical simulation examination. In response to the Sunrise questionnaire, the proponents note that new graduates can expect to earn a salary of $45,000 to $55,000 annually.

Allied Health Care Professionals Who May Share Similar Scopes of Practice

In addition to perfusionists, other allied health professionals who work in similar occupations and settings may share similar scopes of practice, are respiratory care practitioners and cardiovascular technologists.

According to the proponents for regulation, the practice of perfusion is unique to the equipment they use. For example, a respiratory care practitioner (or respiratory therapist) controls the rate of inhaled air by way of a ventilator. A perfusionist performs the same duty but instead uses an artificial lung.

Respiratory Care Practitioners

Part V, chapter 468, F.S., governs the regulation of respiratory therapy by the Board of Respiratory Care. Section 468.352, F.S., defines a "respiratory care practitioner" to mean a licensed respiratory care practitioner who is employed to deliver respiratory care services, under direct supervision, pursuant to an order of a Florida-licensed medical physician or osteopathic physician. Respiratory care services include, but not limited to:

- Administration of drugs, in accordance with protocols;
- Maintenance of equipment to assist and support ventilation and respiration; diagnostic procedures, including measurement of ventilatory volumes, pressures, and flows;
- Specimen collection and analysis of blood for gas transport and acid/base determinations;
- Pulmonary-function testing and other related physiological monitoring of cardiopulmonary systems; and
- Cardiopulmonary resuscitation; insertion and maintenance of artificial airways and intravascular catheters.

[3] The American Board of Cardiovascular Perfusion. Introduction. http://www.abcp.org/introduction.htm (April 2, 2006).

Cardiovascular Technologists

Cardiovascular technologists, who are not regulated in Florida, assist with cardiac catheterization and cardiac resuscitation. They may also specialize in noninvasive peripheral vascular tests such as limb volume changes, oxygen saturation, cerebral circulation, peripheral circulation, and abdominal circulation. Cardiovascular technologists may receive a bachelor's degree, associate degree, or on-the-job training to perform their work.

Cardiovascular technology programs exist at Edison Community College (Ft. Myers), Santa Fe Community College (Gainesville), and Sanford Brown Institute (Tampa). Cardiovascular technologists may receive voluntary certification from the Cardiovascular Credentialing International.

C. SECTION DIRECTORY:

Section 1. Amends s. 456.048, F.S., to specify the financial responsibility requirements for clinical perfusionists.

Sections 2 and 3. Creates ss. 458.3476 and 459.025, F.S., relating to the practice of allopathic medicine and osteopathic medicine respectively: to provide definitions; require a supervising physician to be qualified in the same field as a clinical perfusionist; provide prescribing duties; require a clinical perfusionist to disclose to a patient that he or she is a clinical perfusionist; authorize clinical perfusionist to perform certain medical tasks and services in a protocol; prohibit the prescription, dispense, order, or compound of certain drugs or medical devices; allow a clinical perfusionist to administer certain drugs, fluids, and blood products under the supervision of a physician; exempt a trainee from the requirements of a clinical perfusionist; provide licensure requirements; authorize the board to impose a penalty, denial or suspension of a licensee; authorize the board to appoint persons to provide advice on the rules for the licensure of clinical perfusionist; require the board to adopt rules; provide that hospitals are not obligated to pay certain costs; and authorize the collection and allocation of fees.

Section 4. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to the Department of Health, the bill provides that the Board of Medicine and Board of Osteopathic Medicine, not the department, will set the fees. Revenue projections by the department assume that the two boards will initially impose the application and renewal fee at $1,000, with 225 applicants in year 1 and 10 new applicants in year 2. Revenues were computed based on a $1,000 initial application fee; a $200 initial licensure fee, and a $5 unlicensed activity fee. Revenues in year 3 would include the amounts shown in year 2, plus the first biennial renewal estimated at $235,000 (235 licensees at $1,000) and unlicensed activity fines estimated at $1,175. Revenues for year 4 would duplicate the estimated for year 2.

	1st Year	2nd Year (Annualized/ Recurr.)	3rd Year	4th Year (Annualized/ Recurr.)
Estimated Revenue				
$1000 initial application fee	$225,000	$10,000	$10,000	$10,000
$200 initial licensure fee	$45,000	$2,000	$2,000	$2,000
$5 unlicensed activity fee	$1,125	$50	$1,175	$50
$1000 Renewal Fee			$235,000	
Total Estimated Revenue	$271,125	$12,050	$248,175	$12,050

2. Expenditures:

According to the Department of Health, three half time positions will be required to implement this bill (a 0.5 position for the Board of Medicine, a 0.5 position for the Board of Osteopathic Medicine and a 0.5 position are required for the Bureau of Management Services).

Estimated Expenditures	1st Year	2nd Year (Annualized/ Recurr.)	3rd Year	4th Year (Annualized/ Recurr.)
Salaries				
.5 FTE, RS II, PG 17, Board of Medicine (BOM).	$19,275	$19,275	$19,275	$19,275
.5 FTE, RS II, PG 17, Board of Osteopathic Medicine (BOOM)	$19,275	$19,275	$19,275	$19,275
.5 FTE, RS I, PG 15 (Call Center)	$13,189	$17,586	$17,586	$17,586
Other Personal Services				
Board Member Compensation	$4,000	$4,000	$4,000	$4,000
Expense				
Non-recurring for 2 professional staff	$6,686			
Non-recurring for 1 support staff	$2,791			
Recurring for 2 professional staff w/no travel	$12,806	$12,806	$12,806	$12,806
Recurring for 1support staff	$5,195	$5,195	$5,195	$5,195
Operating Capital Outlay				
2 professional staff	$3,800			
1 support staff	$2,100			
Human Resource Services				
3 FTEs	$1,179	$1,179	$1,179	$1,179
Allocated Expenses	$50,000	$50,000	$50,000	$50,000
Total Estimated Expenditures	$140,296	$129,316	$129,316	$129,316

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Clinical perfusionists in Florida will be subject to an application fee no greater than $1,500 and a biannual license renewal fee no greater than $1,500.

D. FISCAL COMMENTS:

According to the Department of Health (DOH), they did not include in the fiscal projection a .25 FTE attorney position and a support staff position. These positions will be needed at the DOH Prosecution

Services Unit. Additional attorney time and support staff time will be required to prosecute all the violations relating to the new regulation for violation by the Clinical Perfusionists including citations for CE violations. The department projects that the allocated expenses could range from $45,000 to $55,000 or more annually in addition to the direct expenses shown in this analysis. Allocated expenses were estimated at $50,000.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health with adequate rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health has requested that the enactment date be changed to December 1, 2006.

Members of the Board of Medicine and Board of Osteopathic Medicine state that they are not aware of any patient safety issue with perfusionists that would require regulation as a profession under their respective boards.

The Florida Hospital Association (FHA) has stated that historically, the association has opposed additional workforce licensure requirements unless there is a demonstrable need to do so in order to improve patient care. To date, the FHA is unaware of any demonstrated need for the regulation of clinical perfusionists.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

A bill to be entitled

An act relating to clinical perfusionists; amending s. 456.048, F.S.; specifying financial responsibility requirements for clinical perfusionists; creating ss. 458.3476 and 459.025, F.S.; providing definitions; requiring a supervising physician or osteopathic physician to be qualified in the medical areas in which the clinical perfusionist performs; prescribing duties of a clinical perfusionist; requiring a clinical perfusionist to convey to a patient that he or she is a clinical perfusionist; authorizing a clinical perfusionist to perform medical tasks and services within a certain protocol; prohibiting a clinical perfusionist from prescribing, ordering, compounding, or dispensing certain drugs or medical devices; providing that a clinical perfusionist may administer certain drugs, fluids, and blood products under the supervision of a physician or an osteopathic physician; exempting a trainee from the requirements of a clinical perfusionist; requiring approval by the Board of Medicine and the Board of Osteopathic Medicine of training programs for clinical perfusionists; providing licensure requirements; providing provisional licensing requirements; providing for a temporary license as a clinical perfusionist; authorizing each board to impose a penalty against a clinical perfusionist found guilty of or investigated for violating ch. 456, ch. 458, or ch. 459, F.S.; authorizing the chairperson of each board to appoint certain persons to advise the respective boards regarding

rules for the licensure of clinical perfusionists; providing duties of each board; providing for the denial, suspension, or revocation of a license; requiring each board to adopt rules; requiring the Department of Health to allocate collected fees to each board; providing exemptions from clinical perfusionist licensure requirements; providing that hospitals are not obligated to pay certain costs; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.048, Florida Statutes, is amended to read:

456.048 Financial responsibility requirements for certain health care practitioners.--

(1) As a prerequisite for licensure or license renewal, the Board of Acupuncture, the Board of Chiropractic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry shall, by rule, require that all health care practitioners licensed under the respective board, and the Board of Medicine and the Board of Osteopathic Medicine shall, by rule, require that all anesthesiologist assistants licensed under ~~pursuant to~~ s. 458.3475 or s. 459.023 and clinical perfusionists licensed under s. 458.3476 or s. 459.025, and the Board of Nursing shall, by rule, require that advanced registered nurse practitioners certified under s. 464.012, and the department shall, by rule, require that midwives maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a

manner determined by the board or department to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in this state.

(2) The board or department may grant exemptions upon application by practitioners meeting any of the following criteria:

(a) Any person licensed under chapter 457, s. 458.3475, s. 458.3476, s. 459.023, s. 459.025, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices exclusively as an officer, employee, or agent of the Federal Government or of the state or its agencies or its subdivisions. For the purposes of this subsection, an agent of the state, its agencies, or its subdivisions is a person who is eligible for coverage under any self-insurance or insurance program authorized by the provisions of s. 768.28(16) or who is a volunteer under s. 110.501(1).

(b) Any person whose license or certification has become inactive under chapter 457, s. 458.3475, s. 458.3476, s. 459.023, s. 459.025, chapter 460, chapter 461, part I of chapter 464, chapter 466, or chapter 467 and who is not practicing in this state. Any person applying for reactivation of a license must show either that such licensee maintained tail insurance coverage which provided liability coverage for incidents that occurred on or after October 1, 1993, or the initial date of licensure in this state, whichever is later, and incidents that occurred before the date on which the license became inactive; or such licensee must submit an affidavit stating that such licensee has no unsatisfied medical malpractice judgments or

settlements at the time of application for reactivation.

(c) Any person holding a limited license pursuant to s. 456.015, and practicing under the scope of such limited license.

(d) Any person licensed or certified under chapter 457, s. 458.3475, s. 458.3476, s. 459.023, s. 459.025, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals. Such person may engage in the practice of medicine to the extent that such practice is incidental to and a necessary part of duties in connection with the teaching position in the school.

(e) Any person holding an active license or certification under chapter 457, s. 458.3475, s. 458.3476, s. 459.023, s. 459.025, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who is not practicing in this state. If such person initiates or resumes practice in this state, he or she must notify the department of such activity.

(f) Any person who can demonstrate to the board or department that he or she has no malpractice exposure in the state.

(3) Notwithstanding the provisions of this section, the financial responsibility requirements of ss. 458.320 and 459.0085 shall continue to apply to practitioners licensed under those chapters, except for clinical perfusionists licensed under s. 458.3476 or s. 459.025 and anesthesiologist assistants licensed under ~~pursuant to~~ s. 458.3475 or s. 459.023 who must meet the requirements of this section.

Section 2. Section 458.3476, Florida Statutes, is created

to read:

458.3476 Clinical perfusionist.--

(1) DEFINITIONS.--As used in this section, the term:

(a) "Approved program" means a program for the education and training of clinical perfusion which has been approved by the board as provided in subsection (5).

(b) "Board" means the Board of Medicine.

(c) "Clinical perfusionist" means a person who has graduated from an approved program, who is licensed to perform medical services, and who is prescribed, delegated, or supervised by a licensed physician.

(d) "Clinical perfusion" means the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems or other organs, or a combination of those activities, and the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under an order and the supervision of a licensed physician through extracorporeal circulation, long-term clinical support techniques, including extracorporeal carbon dioxide removal and extracorporeal membrane oxygenation, and associated therapeutic and diagnostic technologies, such as counter-pulsation, ventricular assistance, auto-transfusion, blood conservation techniques, myocardial and organ preservation, extracorporeal life support, isolated limb perfusion, therapeutic aphaeresis, and platelet-rich plasma sequestration.

(e) "Continuing medical education" means courses recognized and approved by the board, the American Academy of

Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Board of Cardiovascular Perfusion, or the Accreditation Council on Continuing Medical Education.

(f) "Direct supervision" means on-site, personal supervision by a licensed clinical perfusionist who is present when a procedure is being performed and who is in all instances immediately available to provide assistance and direction to a trainee while clinical perfusion services are being performed.

(g) "Extracorporeal circulation" means the diversion of a patient's blood through a heart-lung machine or a similar device that assumes the functions of the patient's heart, lungs, kidneys, liver, or other organs.

(h) "Trainee" means a person who is currently enrolled in an approved program.

(i) "Perfusion protocols" means perfusion-related policies and protocols developed or approved by a licensed health facility or a physician through collaboration with administrators, licensed clinical perfusionists, and other health care professionals.

(j) "Proficiency examination" means an entry-level examination approved by the board, including examinations administered by the American Board of Cardiovascular Perfusion.

(k) "Provisionally licensed clinical perfusionist" means a person provisionally licensed under this section.

(l) "Supervising physician" means a physician who holds an active license under chapter 458.

(m) "Temporarily licensed clinical perfusionist" means a

person granted a temporary license under this section.

(2) PERFORMANCE OF SUPERVISING PHYSICIANS.--A physician who supervises a clinical perfusionist shall be qualified in the medical areas in which the clinical perfusionist performs.

(3) PERFORMANCE OF CLINICAL PERFUSIONISTS.--

(a) A clinical perfusionist may perform duties established by rule by the board while prescribed by a physician or under the supervision of a physician, including the following duties that are included in the clinical perfusionist's protocol:

1. Perform extracorporeal circulation or clinical support.

2. Perform or administer counter-pulsation.

3. Perform circulatory support and ventricular assistance.

4. Perform extracorporeal membrane oxygenation and extracorporeal life support.

5. Perform blood conservation techniques, auto-transfusion, and blood component sequestration.

6. Perform myocardial preservation.

7. Perform coagulation and hematologic monitoring.

8. Perform physiological monitoring.

9. Perform blood gas analysis and blood chemistry monitoring.

10. Perform induction of hypothermia or hyperthermia with reversal.

11. Perform hemodilution.

12. Perform hemofiltration.

13. Administer blood, blood products, supportive fluids, and anesthetic agents via the extracorporeal circuit.

14. Complete documentation associated with described

duties.

15. Perform isolated limb and organ perfusion.

16. Provide surgical assistance.

17. Perform organ preservation.

18. Perform dialysis while the patient is on clinical bypass.

19. Perform therapeutic aphaeresis.

20. Administer blood, blood products, and supportive fluids via the therapeutic aphaeresis circuit.

21. Perform pacemaker lead and battery analysis.

(b) This section does not prevent third-party payors from reimbursing employers of clinical perfusionists for covered services rendered by the clinical perfusionists.

(c) A clinical perfusionist shall clearly convey to a patient that he or she is a clinical perfusionist.

(d) A clinical perfusionist may perform medical tasks and services within the framework of a written practice protocol developed between the supervising physician and the clinical perfusionist.

(e) A clinical perfusionist may not prescribe, order, compound, or dispense any controlled substance, legend drug, or medical device to any patient. This paragraph does not prohibit a clinical perfusionist from administering legend drugs, controlled substances, or intravenous drugs, fluids, or blood products that are ordered by the physician and administered to a patient while under the orders of the physician.

(4) PERFORMANCE OF TRAINEES.--The practice of a trainee is exempt from the requirements of this section while the trainee

is performing assigned tasks as a trainee in conjunction with an approved program. Before providing clinical perfusion in conjunction with the requirements of an approved program, the trainee shall clearly convey to the patient that he or she is a trainee and is under the direct supervision of a licensed clinical perfusionist.

(5) PROGRAM APPROVAL.--The board shall approve programs for the education and training of clinical perfusionists that meet standards established by board rules. The board may recommend only those programs for clinical perfusionist training that hold full accreditation or provisional accreditation from the Commission on Accreditation of Allied Health Education Programs.

(6) CLINICAL PERFUSIONIST LICENSURE.--

(a) Any person seeking to be licensed as a clinical perfusionist shall apply to the department. The department shall issue a license to any person certified by the board to:

1. Be at least 18 years of age.

2. Have satisfactorily passed a proficiency examination approved by the board. The board, on receipt of an application and application fee, shall waive the examination requirement for an applicant who at the time of application:

a. Is appropriately licensed or certified by another state, territory, or possession of the United States if the requirements for the license or certificate of that state, territory, or possession are the substantial equivalent of the requirements of this section determined by the board;

b. Holds a current certificate as a certified clinical

perfusionist issued by a certifying agency approved by the board that includes as a requirement for certification an examination approved by the board; or

c. Was not a graduate of an accredited program prior to 1981 but met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, if the applicant applies before July 1, 2008, and otherwise complies with the provisions of this section.

3. Be certified in basic cardiac life support.

4. Have completed the application form and remitted an application fee, not to exceed $1,500 as set by the board. An application shall include:

a. A certificate of completion of an approved program.

b. A sworn statement of any prior felony convictions.

c. A sworn statement of any prior discipline or denial of licensure or certification in any state.

d. Two letters of recommendation, one from a physician and one from a certified or licensed clinical perfusionist.

Before July 1, 2007, a person is eligible to apply to the board and receive a license, notwithstanding the requirements of this subsection, if the person was actively engaged in the practice of perfusion consistent with applicable law and if the person was operating cardiopulmonary bypass systems during cardiac surgical cases in a licensed health care facility as the person's primary function and had been operating the system for 8 of the 10 years preceding application for licensure.

(b) A license shall be renewed biennially. Each renewal shall include:

1. A renewal fee, not to exceed $1,500, as set by the board.

2. A sworn statement of no felony convictions in the immediately preceding 2 years.

(c) Each licensed clinical perfusionist shall biennially complete continuing medical education as required by the board.

(d)1. A license as a provisionally licensed clinical perfusionist may be issued by the board to a person who has successfully completed an approved perfusion education program and the filing of an application, payment of an application fee, and the submission of evidence satisfactory to the board of the successful completion of the requisite education requirements.

2. A provisionally licensed clinical perfusionist shall be under the supervision and direction of a licensed clinical perfusionist at all times during which the provisionally licensed clinical perfusionist performs clinical perfusion. Rules adopted by the board governing the supervision and direction may not require the immediate physical presence of the supervising clinical perfusionist.

3. A provisional license is valid for 2 years from the date it is issued and may be extended subject to rule by the board. The application for extension shall be signed by a supervising clinical perfusionist. Upon notification by the approved testing service or the board that any portion of the licensing examination has been failed after the 2-year provisional license term, the provisional license shall be

surrendered to the board.

(e) A license as a temporarily licensed clinical perfusionist may be issued by the department to a person who has successfully completed the licensure application.

(f) The board may impose upon a clinical perfusionist any penalty specified in s. 456.072 or s. 458.331(2) if the clinical perfusionist is found guilty of or is investigated for an act that constitutes a violation of this chapter or chapter 456.

(7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST TO ADVISE THE BOARD.--

(a) The chairperson of the board may appoint a cardiovascular surgeon and a clinical perfusionist to advise the board as to the adoption of rules for the licensure of clinical perfusionists. The board may use a committee structure that is most practicable in order to receive any recommendations to the board regarding rules and all matters relating to clinical perfusionists, including, but not limited to, recommendations to improve safety in the clinical practices of clinical perfusionists.

(b) In addition to its other duties and responsibilities as prescribed by law, the board shall:

1. Recommend to the department the licensure of clinical perfusionists.

2. Develop rules regulating the use of clinical perfusionists under this chapter and chapter 459, except for rules relating to the formulary developed under s. 458.347(4). The board shall also develop rules to ensure that continuity of supervision is maintained in each practice setting. The board

shall consider adopting a proposed rule at the board's regularly scheduled meeting immediately following the submission of the proposed rule. A proposed rule may not be adopted by either the board or the Board of Osteopathic Medicine under s. 459.025 unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules shall be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules.

3. Address concerns and problems of clinical perfusionists to improve safety in the clinical practices of licensed clinical perfusionists.

(c) When the board finds that an applicant for licensure has failed to meet, to the board's satisfaction, each of the requirements for licensure set forth in this section, the board may enter an order to:

1. Refuse to certify the applicant for licensure;

2. Approve the applicant for licensure with restrictions on the scope of practice or license; or

3. Approve the applicant for conditional licensure. The conditions may include placement of the applicant on probation for a period of time and subject to the conditions as the board specifies, including, but not limited to, requiring the applicant to undergo treatment, to attend continuing education courses, or to take corrective action.

(8) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.--The board may deny, suspend, or revoke the license of a clinical perfusionist who the board determines has violated any provision

of this section or any rule adopted pursuant thereto.

(9) RULES.--The board shall adopt rules to administer this section.

(10) FEES.--The department shall allocate the fees collected under this section to the board.

(11) EXEMPTIONS.--

(a) This section may not be construed to limit the practice of a physician licensed under this chapter or a respiratory therapist licensed under this chapter as long as that person does not hold himself or herself out to the public as possessing a license, provisional license, or registration issued under this section or use a professional title protected by this section.

(b) This section may not be construed to limit the practice of nursing or to prevent qualified members of other professions from doing work of a nature consistent with their training and licensure as long as those persons do not hold themselves out to the public as possessing a license, provisional license, or registration issued under this section or use a professional title protected by this section.

(c) A person need not be licensed under this section who:

1. Is licensed in this state under any other law and is engaging in the profession or occupation for which he or she is licensed.

2. Is a qualified person in this state or another state or territory who is employed by the United States Government or an agency thereof while discharging his or her official duties.

3. Is a student providing services regulated under this

section who is:

a. Pursuing a course of study that leads to a degree in a profession regulated under this section.

b. Providing services in a training setting as long as the services and associated activities constitute part of a supervised course of study.

c. Designated by the title "trainee."

4. Is not a resident of this state but offers clinical perfusion services in this state, provided that:

a. The services are performed in this state for no more than 30 days in any calendar year; and

b. The nonresident is licensed or certified by a state or territory of the United States.

(d) Except as stipulated by the board, the exemptions in this subsection do not apply to any person licensed under this section whose license has been revoked or suspended by the board or whose license or certification in another jurisdiction has been revoked or suspended by the licensing or certifying authority in that jurisdiction.

(e) This subsection may not be construed to exempt a person from meeting the minimum standards of performance in professional activities when measured against generally prevailing peer performance, including the undertaking of activities for which the person is not qualified by training or experience.

(12) PAYMENT OR REIMBURSEMENT BY HOSPITALS OF COSTS OF COMPLIANCE.--A hospital is not required to pay for or reimburse any person for the costs of compliance with any requirement of

this section, including costs of continuing education.

Section 3. Section 459.025, Florida Statutes, is created to read:

459.025 Clinical perfusionist.--

(1) DEFINITIONS.--As used in this section, the term:

(a) "Approved program" means a program for the education and training of clinical perfusion which has been approved by the board as provided in subsection (5).

(b) "Board" means the Board of Osteopathic Medicine.

(c) "Clinical perfusionist" means a person who has graduated from an approved program, who is licensed to perform medical services, and who is prescribed, delegated, or supervised by a licensed osteopathic physician.

(d) "Clinical perfusion" means the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems or other organs, or a combination of those activities, and the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under an order and the supervision of a licensed osteopathic physician through extracorporeal circulation, long-term clinical support techniques, including extracorporeal carbon dioxide removal and extracorporeal membrane oxygenation, and associated therapeutic and diagnostic technologies, such as counter-pulsation, ventricular assistance, auto-transfusion, blood conservation techniques, myocardial and organ preservation, extracorporeal life support, isolated limb perfusion, therapeutic aphaeresis, and platelet-rich plasma sequestration.

(e) "Continuing medical education" means courses recognized and approved by the board, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Board of Cardiovascular Perfusion, or the Accreditation Council on Continuing Medical Education.

(f) "Direct supervision" means on-site, personal supervision by a licensed clinical perfusionist who is present when a procedure is being performed and who is in all instances immediately available to provide assistance and direction to a trainee while clinical perfusion services are being performed.

(g) "Extracorporeal circulation" means the diversion of a patient's blood through a heart-lung machine or a similar device that assumes the functions of the patient's heart, lungs, kidneys, liver, or other organs.

(h) "Trainee" means a person who is currently enrolled in an approved program.

(i) "Perfusion protocols" means perfusion-related policies and protocols developed or approved by a licensed health facility or an osteopathic physician through collaboration with administrators, licensed clinical perfusionists, and other health care professionals.

(j) "Proficiency examination" means an entry-level examination approved by the board, including examinations administered by the American Board of Cardiovascular Perfusion.

(k) "Provisionally licensed clinical perfusionist" means a person provisionally licensed under this section.

(l) "Supervising physician" means an osteopathic physician

who holds an active license under chapter 459.

(m) "Temporarily licensed clinical perfusionist" means a person granted a temporary license under this section.

(2) PERFORMANCE OF SUPERVISING PHYSICIANS.--An osteopathic physician who supervises a clinical perfusionist shall be qualified in the medical areas in which the clinical perfusionist performs.

(3) PERFORMANCE OF CLINICAL PERFUSIONISTS.--

(a) A clinical perfusionist may perform duties established by rule by the board while prescribed by an osteopathic physician or under the supervision of an osteopathic physician, including the following duties that are included in the clinical perfusionist's protocol:

1. Perform extracorporeal circulation or clinical support.

2. Perform or administer counter-pulsation.

3. Perform circulatory support and ventricular assistance.

4. Perform extracorporeal membrane oxygenation and extracorporeal life support.

5. Perform blood conservation techniques, auto-transfusion, and blood component sequestration.

6. Perform myocardial preservation.

7. Perform coagulation and hematologic monitoring.

8. Perform physiological monitoring.

9. Perform blood gas analysis and blood chemistry monitoring.

10. Perform induction of hypothermia or hyperthermia with reversal.

11. Perform hemodilution.

12. Perform hemofiltration.

13. Administer blood, blood products, supportive fluids, and anesthetic agents via the extracorporeal circuit.

14. Complete documentation associated with described duties.

15. Perform isolated limb and organ perfusion.

16. Provide surgical assistance.

17. Perform organ preservation.

18. Perform dialysis while the patient is on clinical bypass.

19. Perform therapeutic aphaeresis.

20. Administer blood, blood products, and supportive fluids via the therapeutic aphaeresis circuit.

21. Perform pacemaker lead and battery analysis.

(b) This section does not prevent third-party payors from reimbursing employers of clinical perfusionists for covered services rendered by the clinical perfusionists.

(c) A clinical perfusionist shall clearly convey to a patient that he or she is a clinical perfusionist.

(d) A clinical perfusionist may perform medical tasks and services within the framework of a written practice protocol developed between the supervising physician and the clinical perfusionist.

(e) A clinical perfusionist may not prescribe, order, compound, or dispense any controlled substance, legend drug, or medical device to any patient. This paragraph does not prohibit a clinical perfusionist from administering legend drugs, controlled substances, or intravenous drugs, fluids, or blood

products that are ordered by the osteopathic physician and administered to a patient while under the orders of the physician.

(4) PERFORMANCE OF TRAINEES.--The practice of a trainee is exempt from the requirements of this section while the trainee is performing assigned tasks as a trainee in conjunction with an approved program. Before providing clinical perfusion in conjunction with the requirements of an approved program, the trainee shall clearly convey to the patient that he or she is a trainee and is under the direct supervision of a licensed clinical perfusionist.

(5) PROGRAM APPROVAL.--The board shall approve programs for the education and training of clinical perfusionists that meet standards established by board rules. The board may recommend only those programs for clinical perfusionist training that hold full accreditation or provisional accreditation from the Commission on Accreditation of Allied Health Education Programs.

(6) CLINICAL PERFUSIONIST LICENSURE.--

(a) Any person seeking to be licensed as a clinical perfusionist shall apply to the department. The department shall issue a license to any person certified by the board to:

1. Be at least 18 years of age.

2. Have satisfactorily passed a proficiency examination approved by the board. The board, on receipt of an application and application fee, shall waive the examination requirement for an applicant who at the time of application:

a. Is appropriately licensed or certified by another

state, territory, or possession of the United States if the requirements for the license or certificate of that state, territory, or possession are the substantial equivalent of the requirements of this section determined by the board;

b. Holds a current certificate as a certified clinical perfusionist issued by a certifying agency approved by the board that includes as a requirement for certification an examination approved by the board; or

c. Was not a graduate of an accredited program prior to 1981 but met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, if the applicant applies before July 1, 2008, and otherwise complies with the provisions of this section.

3. Be certified in basic cardiac life support.

4. Have completed the application form and remitted an application fee, not to exceed $1,500 as set by the board. An application shall include:

a. A certificate of completion of an approved program.

b. A sworn statement of any prior felony convictions.

c. A sworn statement of any prior discipline or denial of licensure or certification in any state.

d. Two letters of recommendation, one from an osteopathic physician and one from a certified or licensed clinical perfusionist.

Before July 1, 2007, a person is eligible to apply to the board and receive a license, notwithstanding the requirements of this

subsection, if the person was actively engaged in the practice of perfusion consistent with applicable law and if the person was operating cardiopulmonary bypass systems during cardiac surgical cases in a licensed health care facility as the person's primary function and had been operating the system for 8 of the 10 years preceding application for licensure.

(b) A license shall be renewed biennially. Each renewal shall include:

1. A renewal fee, not to exceed $1,500, as set by the board.

2. A sworn statement of no felony convictions in the immediately preceding 2 years.

(c) Each licensed clinical perfusionist shall biennially complete continuing medical education as required by the board.

(d)1. A license as a provisionally licensed clinical perfusionist may be issued by the board to a person who has successfully completed an approved perfusion education program and the filing of an application, payment of an application fee, and the submission of evidence satisfactory to the board of the successful completion of the requisite education requirements.

2. A provisionally licensed clinical perfusionist shall be under the supervision and direction of a licensed clinical perfusionist at all times during which the provisionally licensed clinical perfusionist performs clinical perfusion. Rules adopted by the board governing the supervision and direction may not require the immediate physical presence of the supervising clinical perfusionist.

3. A provisional license is valid for 2 years from the

date it is issued and may be extended subject to rule by the board. The application for extension shall be signed by a supervising clinical perfusionist. Upon notification by the approved testing service or the board that any portion of the licensing examination has been failed after the 2-year provisional license term, the provisional license shall be surrendered to the board.

(e) A license as a temporarily licensed clinical perfusionist may be issued by the department to a person who has successfully completed the licensure application.

(f) The board may impose upon a clinical perfusionist any penalty specified in s. 456.072 or s. 458.331(2) if the clinical perfusionist is found guilty of or is investigated for an act that constitutes a violation of this chapter or chapter 456.

(7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST TO ADVISE THE BOARD.--

(a) The chairperson of the board may appoint a cardiovascular surgeon and a clinical perfusionist to advise the board as to the adoption of rules for the licensure of clinical perfusionists. The board may use a committee structure that is most practicable in order to receive any recommendations to the board regarding rules and all matters relating to clinical perfusionists, including, but not limited to, recommendations to improve safety in the clinical practices of clinical perfusionists.

(b) In addition to its other duties and responsibilities as prescribed by law, the board shall:

1. Recommend to the department the licensure of clinical

perfusionists.

2. Develop rules regulating the use of clinical perfusionists under this chapter and chapter 458, except for rules relating to the formulary developed under s. 458.347(4). The board shall also develop rules to ensure that continuity of supervision is maintained in each practice setting. The board shall consider adopting a proposed rule at the board's regularly scheduled meeting immediately following the submission of the proposed rule. A proposed rule may not be adopted by either the board or the Board of Medicine under s. 458.3476 unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules shall be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules.

3. Address concerns and problems of clinical perfusionists to improve safety in the clinical practices of licensed clinical perfusionists.

(c) When the board finds that an applicant for licensure has failed to meet, to the board's satisfaction, each of the requirements for licensure set forth in this section, the board may enter an order to:

1. Refuse to certify the applicant for licensure;

2. Approve the applicant for licensure with restrictions on the scope of practice or license; or

3. Approve the applicant for conditional licensure. The conditions may include placement of the applicant on probation for a period of time and subject to the conditions as the board

specifies, including, but not limited to, requiring the applicant to undergo treatment, to attend continuing education courses, or to take corrective action.

(8) DENIAL, SUSPENSION, OR REVOCATION OF LICENSURE.--The board may deny, suspend, or revoke the license of a clinical perfusionist who the board determines has violated any provision of this section or any rule adopted pursuant thereto.

(9) RULES.--The board shall adopt rules to administer this section.

(10) FEES.--The department shall allocate the fees collected under this section to the board.

(11) EXEMPTIONS.--

(a) This section may not be construed to limit the practice of an osteopathic physician licensed under this chapter or a respiratory therapist licensed under chapter 468 as long as that person does not hold himself or herself out to the public as possessing a license, provisional license, or registration issued under this section or use a professional title protected by this section.

(b) This section may not be construed to limit the practice of nursing or to prevent qualified members of other professions from doing work of a nature consistent with their training and licensure as long as those persons do not hold themselves out to the public as possessing a license, provisional license, or registration issued under this section or use a professional title protected by this section.

(c) A person need not be licensed under this section who:

1. Is licensed in this state under any other law and is

engaging in the profession or occupation for which he or she is licensed.

2. Is a qualified person in this state or another state or territory who is employed by the United States Government or an agency thereof while discharging his or her official duties.

3. Is a student providing services regulated under this section who is:

a. Pursuing a course of study that leads to a degree in a profession regulated under this section.

b. Providing services in a training setting as long as the services and associated activities constitute part of a supervised course of study.

c. Designated by the title "trainee."

4. Is not a resident of this state but offers clinical perfusion services in this state, provided that:

a. The services are performed in this state for no more than 30 days in any calendar year; and

b. The nonresident is licensed or certified by a state or territory of the United States.

(d) Except as stipulated by the board, the exemptions in this subsection do not apply to any person licensed under this section whose license has been revoked or suspended by the board or whose license or certification in another jurisdiction has been revoked or suspended by the licensing or certifying authority in that jurisdiction.

(e) This subsection may not be construed to exempt a person from meeting the minimum standards of performance in professional activities when measured against generally

prevailing peer performance, including the undertaking of activities for which the person is not qualified by training or experience.

(12) PAYMENT OR REIMBURSEMENT BY HOSPITALS OF COSTS OF COMPLIANCE.--A hospital is not required to pay for or reimburse any person for the costs of compliance with any requirement of this section, including costs of continuing education.

Section 4. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 1625**

COUNCIL/COMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

Council/Committee hearing bill: Health Care Regulation

Representative(s) Kottkamp offered the following:

Amendment (with directory and title amendments)

Remove line(s) 736 and insert:

Section 4. This act shall take effect December 1, 2006.